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U-M Data Warehouse

# **Human Subjects Research Data Dictionary**

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Michigan Administrative Information Services  
University of Michigan  
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### **Comments and Suggestions**

Your feedback is very important to us. As a U-M Data Warehouse user, we encourage you to tell us what you like or dislike about this Data Dictionary. Your comments and suggestions will help us improve this and other MAIS documentation for you in the future.

Please e-mail your comments and suggestions to [maishelpdesk@umich.edu](mailto:maishelpdesk@umich.edu). Thank you.

## Contents

Human Subjects Research Tables Diagram	1
Human Subjects Research Tables Description	5
Human Subjects Research Data Element Dictionary	7

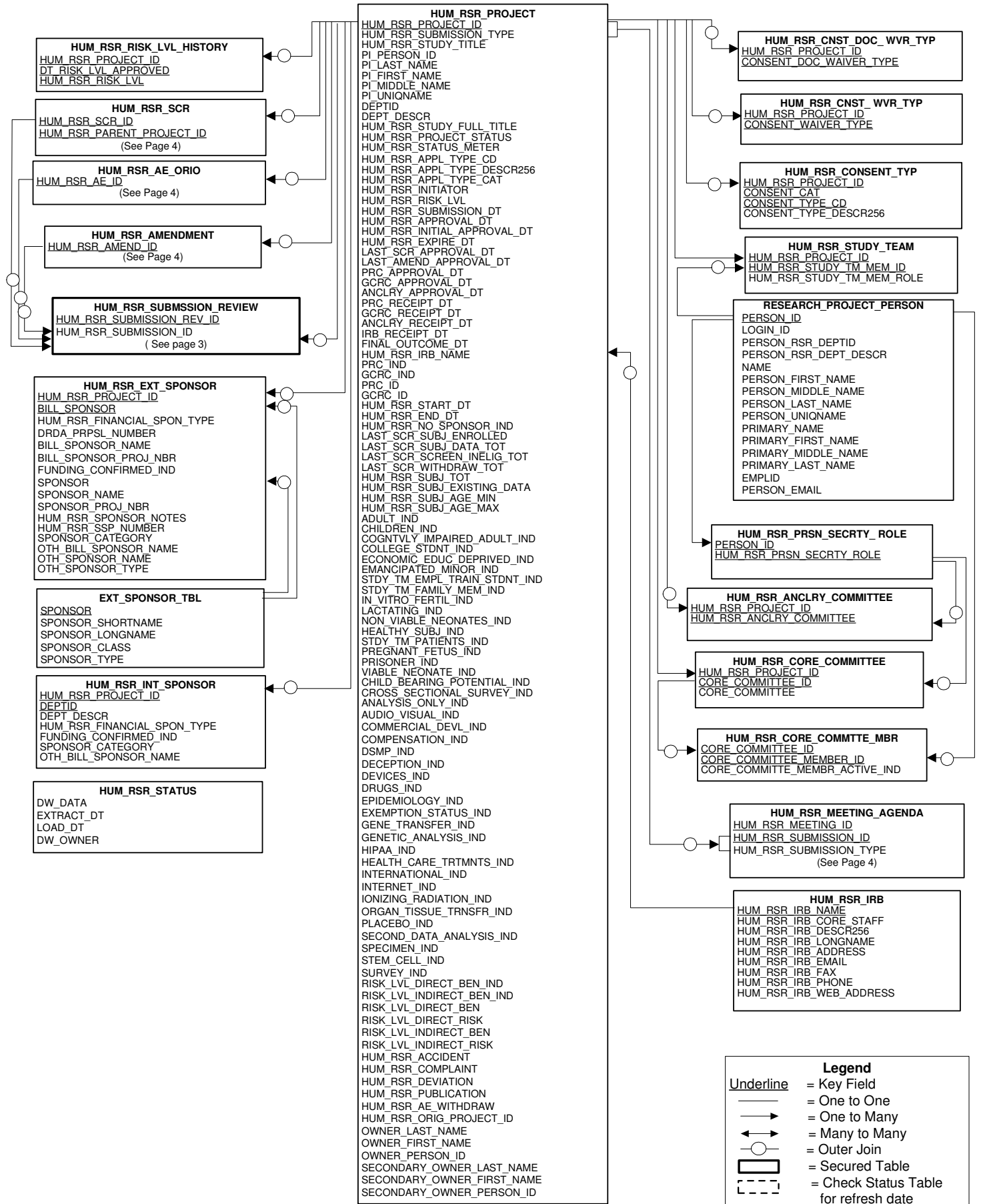
# Human Subjects Research Tables Diagram

The Human Subjects Research Tables Diagram illustrates the *logical* relationships among the Human Subjects Research tables. A logical link (connecting line) between two tables indicates that there is a direct data relationship between the two tables. Physically, any tables with a common element can be joined. However, two tables with common elements may not necessarily have logical links to one another. Joining tables without logical links may produce undesired results; a thorough understanding of the data is needed to guarantee accurate results.

All tables within a data set are not necessarily refreshed on the same schedule. It is ***extremely important*** to query the status table to determine when the data in each table was last refreshed and to determine the impact this will have on query results.

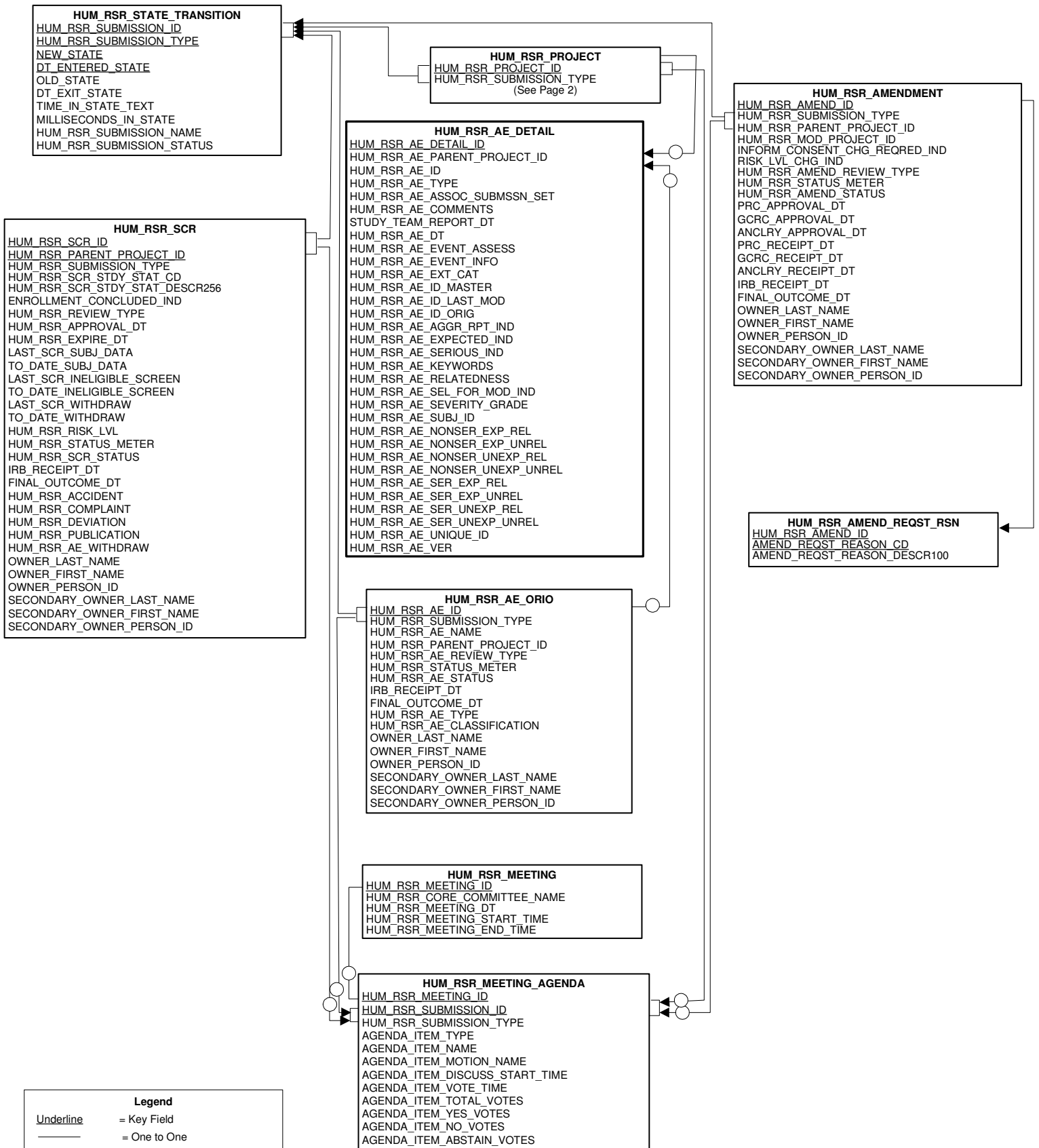
*Note: The Human Subjects Research Tables Diagram is shown on pages 2 through 4*

# Human Subjects Research Information





# Human Subjects Research Meeting and State Information



**Legend**

Underline = Key Field

— = One to One

—> = One to Many

←> = Many to Many

○ = Outer Join

▭ = Secured Table

- - - = Check Status Table for refresh date

## Human Subjects Research Tables Description

The Human Subjects Research Tables Description provides the following information for each table in the U-M Data Warehouse Human Subjects Research data set:

<i>Physical Table Name</i>	Name for the table you can use in SQL queries.
<i>Logical Table Name</i>	Descriptive name of the table.
<i>Data Set Locations</i>	The names of the data sets in which the table resides.
<i>Table Description</i>	Description of the table.

The tables are ordered alphabetically by table physical name.

Physical Table Name	Logical Table Name	Data Set Locations	Table Description
EXT_SPONSOR_TBL	External Sponsor Table	ERESDW1	Information about external sponsors such as name and sponsor category.
HUM_RSR_AE_DETAIL	Human Research Adverse Event Detail	ERESDW1	Detailed information about all adverse events reported for approved human subject research.
HUM_RSR_AE_ORIO	Human Research Adverse Event (AE) or Other Reportable Incident Occurrence (ORIO)	ERESDW1	Information about adverse events or other reportable incidents or occurrences related to a human research study.
HUM_RSR_AMEND_REQST_RSN	Human Research Amendment Request Reason	ERESDW1	Information about amendment request reasons related to an amendment for a human research study.
HUM_RSR_AMENDMENT	Human Research Amendment	ERESDW1	Information about amendments related to a human research study.
HUM_RSR_ANCLRY_COMMITTEE	Human Research Ancillary Committee	ERESDW1	Information about ancillary committees related to a human research study.
HUM_RSR_CNST_DOC_WVR_TYP	Human Research Consent Document Waiver Type	ERESDW1	Information about the types of consent document waivers related to a human research study.
HUM_RSR_CNST_WVR_TYP	Human Research Consent Waiver Type	ERESDW1	Information about the types of consent waivers related to a human research study.
HUM_RSR_CONSENT_TYP	Human Research Consent Type	ERESDW1	Information about the types of consent related to a specific human research study.
HUM_RSR_CORE_COMMITTEE	Human Research Core Committee	ERESDW1	Information about the core committees related to a human research study.
HUM_RSR_CORE_COMMTTE_MBR	Human Research Core Committee Member	ERESDW1	Information about membership in IRB (Institutional Review Board) committees.
HUM_RSR_DEVICE	Human Research Device	ERESDW1	Information about devices used in a human research study.
HUM_RSR_DRUG	Human Research Drug	ERESDW1	Information about drugs used in a human research study.
HUM_RSR_EXT_SPONSOR	Human Research External Sponsor	ERESDW1	Information about external sponsors related to a human research study, such as DRDA (Division of Research Development Administration) proposal number, direct sponsor and prime sponsor.

Physical Table Name	Logical Table Name	Data Set Locations	Table Description
HUM_RSR_INT_SPONSOR	Human Research Internal Sponsor	ERESDW1	Information about internal sponsors related to a human research study.
HUM_RSR_IRB	Human Research Institutional Review Board	ERESDW1	Information about IRBs (Institutional Review Boards) on campus.
HUM_RSR_MEETING	Human Research Meeting	ERESDW1	Information about scheduled IRB (Institutional Review Board) meetings.
HUM_RSR_MEETING_AGENDA	Human Research Meeting Agenda	ERESDW1	Information about meeting agenda items assigned to a meeting related to a human research study.
HUM_RSR_PROJ_COMP	Human Research Project Compensation	ERESDW1	Information about compensation given to subjects participating in a study.
HUM_RSR_PROJ_FUNCTION	Human Research Project Function	ERESDW1	Information about the research functions that will be performed on human research studies.
HUM_RSR_PROJ_LOCATION	Human Research Project Location	ERESDW1	Information about locations where human research studies will be conducted.
HUM_RSR_PROJ_SUBJ_COST	Human Research Project Subject Cost	ERESDW1	Information about what costs could be incurred by subjects participating in a study.
HUM_RSR_PROJECT	Human Research Project	ERESDW1	Information about human research studies.
HUM_RSR_PROJECT_DETAIL	Human Research Project Detail	ERESDW1	Detailed information about human research studies.
HUM_RSR_PRSN_SECRTY_ROLE	Human Research Person Security Role	ERESDW1	The person's security role within the human research system.
HUM_RSR_RISK_LVL_HISTORY	Human Research Risk Level history	ERESDW1	Information about the risk level history related to a human research study.
HUM_RSR_SCR	Human Research Scheduled Continuing Review	ERESDW1	Information about the scheduled continuing reviews related to a human research study.
HUM_RSR_STATE_TRANSITION	Human Research State Transition	ERESDW1	Information about the time between state transitions related to a human research study.
HUM_RSR_STATUS	Human Research Study Tables Status	ERESDW1	Review status of the human research study submissions.
HUM_RSR_STUDY_TEAM	Human Research Study Team	ERESDW1	Information about study teams related to a human research study.
HUM_RSR_SUBMSSION_REVIEW	Human Research Submission Review	ERESDW1	Information about reviews that are completed for a human research submission.
HUM_RSR_UM_PROJ_FACILITY	Human Research University of Michigan Project Facility	ERESDW1	Information about U of M facilities where human research studies will be conducted.
RESEARCH_PROJECT_PERSON	Research Project Person	ERESDW1	Information about people related to a research study.

## Human Subjects Research Data Element Dictionary

The Human Subjects Research Data Element Dictionary contains all the elements found in the U-M Data Warehouse Human Subjects Research Tables, ordered alphabetically by element name. Here is a description of the information that the dictionary provides for each element:

<i>Physical Element Name</i>	Name for the element you can use in SQL queries.	
<i>Logical Element Name</i>	Descriptive name of the element.	
<i>Format Type</i>	Type of value of the element (for example: character, number, or date). <i>Note:</i> If the format type for an element is character or date, you must enclose the variable value in single quotes when entering queries.	
<i>Format Length</i>	Total length of the element. For data elements in the format “number,number”, the first number represents the total length of the element. The second number represents the number of digits to the right of the decimal.	
<i>Data Sets</i>	The names of the data sets that contain the element.	
<i>Table Locations</i>	The names of the tables in which the element is located.	
<i>Security Code</i>	The level of security imposed on the element. Values are:	
	P	Public data            Data with no access restriction that may be released to the general public.
	R	Private/ Confidential data    Data available to University employees who need to access these data to perform their official University duties. Unless otherwise noted, all institutional data is designated as Private/Confidential.
	S	Sensitive data        Data available only to University employees who have specific authorization for access. Never release sensitive data in a manner that enables identifying data element values with a specific person or persons.
<i>Element Definition</i>	Description of the element.	
<i>Examples of Valid Values</i>	Either the specific codes that are valid for the element, or samples of the kind of values for the element.	

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
ADULT_IND	Adult Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether adults are part of a specific research study.	Y = Yes; N = No; null
AGENDA_ITEM_ABSTAIN_VOTES	Agenda Item Abstained Votes Count	Number	4	ERESDW1	HUM_RSR_MEETING_AGENDA	R	A number representing the count of abstained votes for a meeting agenda item related to a research study.	0; 1; 3
AGENDA_ITEM_DISCUSS_START_TIME	Agenda Item Discussion Start Time	Date		ERESDW1	HUM_RSR_MEETING_AGENDA	R	The time at which discussion of an agenda item is started during a meeting.	03/29/2005 11:00:00 AM; 04/14/2005 12:09:00 PM; 05/05/2005 12:10:00 PM
AGENDA_ITEM_MOTION_NAME	Agenda Item Motion Name	Character	256	ERESDW1	HUM_RSR_MEETING_AGENDA	R	A textual description of the motion related to an agenda item.	Action Deferred Pending Core Committee; Approved; Approved with Contingencies
AGENDA_ITEM_NAME	Agenda Item Name	Character	256	ERESDW1	HUM_RSR_MEETING_AGENDA	R	The agenda item name related to a research study assigned to an agenda for a meeting.	A survey of people: HUM00001 Amendment
AGENDA_ITEM_NO_VOTES	Agenda Item No Votes Count	Number	4	ERESDW1	HUM_RSR_MEETING_AGENDA	R	A number representing the count of no votes for a meeting agenda item related to a research study.	0; 8; 12
AGENDA_ITEM_TOTAL_VOTES	Agenda Item Total Votes Count	Number	4	ERESDW1	HUM_RSR_MEETING_AGENDA	R	A number representing the total count of all types of votes for a meeting agenda item related to a research study.	8; 10; 17
AGENDA_ITEM_TYPE	Agenda Item Type Text	Character	256	ERESDW1	HUM_RSR_MEETING_AGENDA	R	A textual description of the type of agenda item assigned to an agenda for a meeting.	Amendment; New Study; Deferred Study

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
AGENDA_ITEM_VOTE_TIME	Agenda Item Vote Time	Date		ERESDW1	HUM_RSR_MEETING_AGENDA	R	The time a committee vote was taken for a meeting agenda item (submission).	03/29/2005 11:00:00 AM; 04/14/2005 12:09:00 PM; 05/05/2005 12:10:00 PM
AGENDA_ITEM_YES_VOTES	Agenda Item Yes Votes Count	Number	4	ERESDW1	HUM_RSR_MEETING_AGENDA	R	A number representing the count of yes votes for a meeting agenda item related to a research study.	0; 8; 17
AMEND_REQST_REASON_DESCR100	Amendment Request Reason Description	Character	100	ERESDW1	HUM_RSR_AMEND_REQST_RSN	R	A textual description of the reason an amendment for a research study was requested.	Required for conversion to eResearch; Response to a regulatory requirement
AMEND_REQST_REASON_CD	Amendment Request Reason Code	Character	30	ERESDW1	HUM_RSR_AMEND_REQST_RSN	R	A code representing the reason an amendment for a research study was requested.	Conversion; Regulatory
ANALYSIS_ONLY_IND	Analysis Only Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating that only data analysis will be performed for a specific research study. No direct interaction with subjects will occur.	Y = Yes; N = No; null
ANCLRY_APPROVAL_DT	Ancillary Committees Approval Date	Date		ERESDW1	HUM_RSR_AMENDMENT HUM_RSR_PROJECT	R	The date that the submission was approved by all required Ancillary Committees.	03/29/2005; 04/14/2005; 05/05/2005
ANCLRY_RECEIPT_DT	Ancillary Committees Receipt Date	Date		ERESDW1	HUM_RSR_AMENDMENT HUM_RSR_PROJECT	R	The date that the submission was received by all required Ancillary Committees.	03/29/2005; 04/14/2005; 05/05/2005
ANTICIPATED_SUBJECT_COST	Anticipated Subject Cost Description	Character	130	ERESDW1	HUM_RSR_PROJ_SUBJ_COST	R	A textual description of the anticipated cost of a research subject.	Lost wages; Drugs, biologics, or devices; Parking; Travel; Lodging; Research-related services/procedures; No anticipated costs

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
ANTICIPATED_SUBJECT_COST_OTHER	Anticipated Subject Cost Other Description	Character	256	ERESDW1	HUM_RSR_PROJ_SUBJ_COST	R	A textual description of the anticipated costs of a research subject other than the standard costs.	Standard of care; Cost of Internet Service Provider (for Web-based participants)
AUDIO_VISUAL_IND	Audio Visual Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether audio visual equipment is used as a part of a specific research study.	Y = Yes; N = No; null
BILL_SPONSOR	Billing Sponsor Code	Character	6	ERESDW1	HUM_RSR_EXT_SPONSOR	R	A code representing the awarding department.	288000 = Ford Motor Company; 573040 = Michigan, State of, Education, Department of; 895700 = Health and Human Services, Department of-National Institutes of Health
BILL_SPONSOR_NAME	Billing Sponsor Name	Character	256	ERESDW1	HUM_RSR_EXT_SPONSOR	R	The name of the billing external sponsor for a research study.	Berlex Laboratories, Inc.; Centocor, Inc.; Ford Motor Company
BILL_SPONSOR_PROJ_NBR	Billing Sponsor Project Number	Character	256	ERESDW1	HUM_RSR_EXT_SPONSOR	R	A number, assigned by the billing sponsor, which uniquely identifies a research study. This information is applicable only for converted IRBM studies.	CA 183001; C0168T45; 148650
CHILD_BEARING_POTENTIAL_IND	Child Bearing Potential Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether women with child bearing potential are part of a specific research study.	Y = Yes; N = No; null
CHILDREN_IND	Children Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether children are part of a specific research study.	Y = Yes; N = No; null
COGNTVLY_IMPAIRED_ADULT_IND	Cognitively Impaired Adult Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether cognitively impaired adults are part of a specific research study.	Y = Yes; N = No; null

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
COLLEGE_STDNT_IND	College Student Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether college students are part of a specific research study.	Y = Yes; N = No; null
COMMERCIAL_DEVL_IND	Commercial Development Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether commercial development is considered as a part of a specific research study.	Y = Yes; N = No; null
COMPENSATION_IND	Compensation Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether compensation is offered for participation in a specific research study.	Y = Yes; N = No; null
COMPENSATION_TYPE	Compensation Type Description	Character	50	ERESDW1	HUM_RSR_PROJ_COMP	R	A textual description of the type of compensation.	Reimbursements for expenses, such as travel; Gift certificates; Token gift; Cash/Check
COMPENSATION_TYPE_OTHER	Compensation Type Other Description	Character	256	ERESDW1	HUM_RSR_PROJ_COMP	R	A textual description of an alternative type of compensation.	Gift certificate to local department store.
CONSENT_CAT	Consent Category	Character	8	ERESDW1	HUM_RSR_CONSENT_TYP	R	A code representing a high level grouping of consent types related to a research study.	ADULT; CHILD
CONSENT_DOC_WAIVER_TYPE	Consent Document Waiver Type Text	Character	256	ERESDW1	HUM_RSR_CNST_DOC_WVR_TYP	R	A textual description used to identify the type of consent document waiver for a specific research study.	The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from breach of confidentiality.
CONSENT_TYPE_CD	Consent Type Code	Character	50	ERESDW1	HUM_RSR_CONSENT_TYP	R	A code representing the type of consent required for a subject on a research study.	Alteration; Written
CONSENT_TYPE_DESCR256	Consent Type Description	Character	256	ERESDW1	HUM_RSR_CONSENT_TYP	R	A textual description of the code representing the type of consent required for a subject on a research study.	Request for alteration of informed consent requirement; Comprehensive written

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
CONSENT_WAIVER_TYPE	Consent Waiver Type Text	Character	256	ERESDW1	HUM_RSR_CNST_WVR_TYP	R	A textual description used to identify the type of consent waiver for a specific research study.	An alteration to the informed consent requirement for ALL of the project; Waiver of informed consent for ALL of the project
CORE_COMMITTE_MEMBR_ACTIVE_IND	Core Committee Member Active Indicator Code	Character	1	ERESDW1	HUM_RSR_CORE_COMMTTE_MBR	R	A code indicating whether a core committee member is active or not.	Y = Yes; N = No; null
CORE_COMMITTEE	Core Committee Description	Character	30	ERESDW1	HUM_RSR_CORE_COMMITTEE	R	A code representing a core committee related to a research study.	Core IRB BehavSciStaff; Core PRC Staff; Core GCRC Staff
CORE_COMMITTEE_MEMBER_ID	Core Committee Member Identification Code	Character	20	ERESDW1	HUM_RSR_CORE_COMMTTE_MBR	R	A code identifying a core committee member. For U of M employees this will be the UMID.	12345678
CORE_COMMITTEE_ID	Core Committee Identification Code	Character	20	ERESDW1	HUM_RSR_CORE_COMMITTEE HUM_RSR_CORE_COMMTTE_MBR	R	A code identifying a particular core committee.	ID0000000003; ID0000000004; ID0000000005
CROSS_SECTIONAL_SURVEY_IND	Cross Sectional Survey Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether a cross sectional survey is a part of a specific research study.	Y = Yes; N = No; null
DECEPTION_IND	Deception Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether deception will be used as part of a specific research study.	Y = Yes; N = No; null
DEPT_DESCR	Department Description	Character	30	ERESDW1	HUM_RSR_INT_SPONSOR HUM_RSR_PROJECT RESEARCH_PROJECT_PERSON	R	A textual description of the code that identifies each academic or administrative unit that has programmatic, operational and fiscal (including budgetary) responsibility.	Physics Department; College of Lit, Science & Arts; UMH Administration;
DEPTID	Department Identification	Character	10	ERESDW1	HUM_RSR_INT_SPONSOR HUM_RSR_PROJECT RESEARCH_PROJECT_PERSON	R	A code that identifies each academic or administrative unit that has programmatic, operational and fiscal (including budgetary) responsibility.	184500 = Physics Department; 170000 = College of Lit, Science & Arts; 311679 = UMH Administration

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
DEVICES_IND	Devices Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether devices are used as a part of a specific research study.	Y = Yes; N = No; null
DIRECT_SPONSOR_ID	Direct Research External Sponsor	Character	6	ERESDW1	HUM_RSR_EXT_SPONSOR	R	A code identifying the direct external sponsor for a research study. This code is defined by DRDA (Division of Research Development Administration) for this sponsor.	080750; 101370; 288000
DRDA_PRPSL_NUMBER	DRDA Proposal Number	Character	8	ERESDW1	HUM_RSR_EXT_SPONSOR	R	The DRDA (Division of Research Development Administration) number which uniquely identifies a research study.	03-4004; Reported; 05-1234
DRUGS_IND	Drugs Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether drugs are used as a part of a specific research study.	Y = Yes; N = No; null
DSMP_IND	Data Safety Monitoring Plan Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether a DSMP(Data Safety Monitoring Plan) is required as a part of a specific research study.	Y = Yes; N = No; null
DT_ENTERED_STATE	Date Entered State	Date		ERESDW1	HUM_RSR_STATE_TRANSITION	R	The date on which a research study entered a particular state.	03/29/2005; 04/14/2005; 05/05/2005
DT_EXIT_STATE	Date Exit State	Date		ERESDW1	HUM_RSR_STATE_TRANSITION	R	The date on which a research study exited a particular state.	03/29/2005; 04/14/2005; 05/05/2005
DT_RISK_LVL_APPROVED	Date Risk Level Approved	Date		ERESDW1	HUM_RSR_RISK_LVL_HISTORY	R	The date on which a particular risk level is approved for a research study.	03/29/2005; 04/14/2005; 05/05/2005
DW_DATA	Data Warehouse Data	Character	50	ERESDW1	HUM_RSR_STATUS	R	The names of the data warehouse objects that were loaded. These objects could be a dataset, a group of tables, or an individual table.	eResearch Tables
DW_OWNER	Data Warehouse Owner	Character	8	ERESDW1	HUM_RSR_STATUS	R	The owner (oracle schema) of the data warehouse objects that were loaded.	eresdw1

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
ECONOMIC_EDUC_DEPRIVED_IND	Economically or Educationally Deprived Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether economically or educationally deprived individuals are part of a specific research study.	Y = Yes; N = No; null
EMANCIPATED_MINOR_IND	Emancipated Minor Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether emancipated minors are a part of a specific research study.	Y = Yes; N = No; null
EMPLID	Employee Identification	Character	11	ERESDW1	RESEARCH_PROJECT_PERSON	R	A system assigned number to uniquely identify a person at U of M. Commonly referred to as UMID.	25582542
ENROLLMENT_CONCLUDED_IND	Enrollment Concluded Indicator Code	Character	1	ERESDW1	HUM_RSR_SCR	R	A code indicating whether enrollment in a research project is concluded or not.	Y = Yes; N = No; null
EPIDEMIOLOGY_IND	Epidemiology Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether an epidemiology study is a part of a specific research study.	Y = Yes; N = No; null
EXEMPTION_STATUS_IND	Exemption Status Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating that an exemption has been requested for a specific research study.	Y = Yes; N = No; null
EXTRACT_DT	Extract Date	Date		ERESDW1	HUM_RSR_STATUS	R	The date and time at which the data was extracted from the source system.	07/22/2000 7:06:17 PM
FDA_APPROVAL_STATUS	Food and Drug Administration Approval Status	Character	20	ERESDW1	HUM_RSR_DEVICE HUM_RSR_DRUG	R	A code representing the status of FDA (Food and Drug Administration ) approval for a drug or device used in a research study.	FDA Approved; Non-FDA Approved
FINAL_OUTCOME_DT	Final Outcome Date	Date		ERESDW1	HUM_RSR_AE_ORIO HUM_RSR_AMENDMENT HUM_RSR_PROJECT HUM_RSR_SCR	R	The date that the final determination about a submission is made by the IRB (Institutional Review Board).	03/29/2005; 04/14/2005; 05/05/2005
FREE_HEALTH_CARE_PROCEDURE	Free Health Care Procedure Text	Character	4000	ERESDW1	HUM_RSR_PROJECT_DETAIL	R	A textual description of a health care procedure that is provided at no charge.	Please refer to the protocol section "Study Procedures."
FUNDING_CONFIRMED_IND	Funding Confirmed Indicator Code	Character	1	ERESDW1	HUM_RSR_EXT_SPONSOR HUM_RSR_INT_SPONSOR	R	A code indicating whether funding from an external or internal sponsor is confirmed for a research study.	Y = Yes; N = No; Null

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
GCRC_APPROVAL_DT	General Clinical Research Center Approval Date	Date		ERESDW1	HUM_RSR_AMENDMENT HUM_RSR_PROJECT	R	The date that the submission was approved by the GCRC (General Clinical Research Center)	03/29/2005; 04/14/2005; 05/05/2005
GCRC_ID	General Clinical Research Center Identification	Character	256	ERESDW1	HUM_RSR_PROJECT	R	The tracking number for a GCRC (General Clinical Research Center) study which is a part of a specific research study. This information is applicable only for converted IRBMED studies.	2139; 2166; 2173
GCRC_RECEIPT_DT	General Clinical Research Center Receipt Date	Date		ERESDW1	HUM_RSR_AMENDMENT HUM_RSR_PROJECT	R	The date that the submission was received by the GCRC (General Clinical Research Center).	03/29/2005; 04/14/2005; 05/05/2005
GENE_TRANSFER_IND	Gene Transfer Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether genes are transferred as part of the protocol for a specific research study.	Y = Yes; N = No; null
GENETIC_ANALYSIS_IND	Genetic Analysis Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether a genetic analysis is done as a part of the protocol for a specific research study.	Y = Yes; N = No; null
HEALTH_CARE_TRTMNTS_IND	Health Care Treatment Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether a health care treatment is considered as part of the protocol for a specific research study.	Y = Yes; N = No; null
HEALTHY_SUBJ_IND	Healthy Subject Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether healthy subjects will be recruited for a specific research study.	Y = Yes; N = No; null
HIPAA_IND	Health Insurance Portability and Accountability Act Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether Health Insurance Portability and Accountability Act (HIPAA) considerations need to be taken into account in a specific research study.	Y = Yes; N = No; null
HOME_CARE_IND	Home Care Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT_DETAIL	R	A code indicating whether home care will be required for a human subjects study.	Y = Yes; N = No; null
HUM_RSR_ACCIDENT	Human Research Accident Count	Number	8	ERESDW1	HUM_RSR_PROJECT HUM_RSR_SCR	R	A number representing the count of accidents associated with a research project.	0; 5; 47

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
HUM_RSR_AE_CLASSIFICATION	Human Research Adverse Event Classification	Character	4	ERESDW1	HUM_RSR_AE_ORIO	R	A code representing a high level grouping of adverse events related to a research study.	AE; ORIO
HUM_RSR_AE_AGGR_RPT_IND	Human Research Adverse Event Aggregate Report Indicator Code	Character	1	ERESDW1	HUM_RSR_AE_DETAIL	R	A code indicating whether an adverse event report is an aggregate report.	Y = Yes; N = No; null
HUM_RSR_AE_ASSOC_SUBMSSN_SET	Human Research Associated Adverse Event Submission Set Code	Character	20	ERESDW1	HUM_RSR_AE_DETAIL	R	A code identifying all adverse events related to a master adverse event detail row. This field is only populated where HUM_RSR_AE_VER = "Master"	ID0000000097; ID0000000102; ID0000000098
HUM_RSR_AE_COMMENTS	Human Research Adverse Event Comments	Character	256	ERESDW1	HUM_RSR_AE_DETAIL	R	A line of text containing comments related to an adverse event.	Death; fainted
HUM_RSR_AE_DETAIL_ID	Human Research Adverse Event Detail Identification Code	Character	20	ERESDW1	HUM_RSR_AE_DETAIL	R	A code identifying the detail of an adverse event.	ID000000001; ADV00000009 (for data that was converted December 2006)
HUM_RSR_AE_DT	Human Research Adverse Event Date	Date		ERESDW1	HUM_RSR_AE_DETAIL	R	The date of a human research adverse event.	10/2/2006; 11/15/2006
HUM_RSR_AE_EVENT_ASSESS	Human Research Adverse Event Assessment Code	Character	35	ERESDW1	HUM_RSR_AE_DETAIL	R	A code identifying an assessment for a human research adverse event.	Serious, Unexpected, Related; Non-Serious, Expected, Related
HUM_RSR_AE_EVENT_INFO	Human Research Adverse Event Information Text	Character	256	ERESDW1	HUM_RSR_AE_DETAIL	R	A textual description containing information about a human research adverse event.	Headaches were reported by xx participants of the research study. This was brought to the researchers attention during interviews.
HUM_RSR_AE_EXPECTED_IND	Human Research Adverse Event Expected Indicator Code	Character	1	ERESDW1	HUM_RSR_AE_DETAIL	R	A code indicating whether a human research adverse event might be expected.	Y = Yes; N = No; null
HUM_RSR_AE_EXT_CAT	Human Research Adverse Event External Category	Character	256	ERESDW1	HUM_RSR_AE_DETAIL	R	A textual description containing information about the external category of a human research adverse event.	Sister Site; Clinical Care; Different Study

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
HUM_RSR_AE_ID	Human Research Adverse Event Identification Code	Character	20	ERESDW1	HUM_RSR_AE_DETAIL HUM_RSR_AE_ORIO	R	A code uniquely identifying an adverse event related to a research study. In the case of the HUM_RSR_AE_DETAIL table this field is NOT populated where HUM_RER_AE_VER = "Master"	Adv00000009; Adv00000013; Adv00000029
HUM_RSR_AE_ID_LAST_MOD	Human Research Adverse Event Last Modified Identification Code	Character	20	ERESDW1	HUM_RSR_AE_DETAIL	R	A code identifying the adverse event detail row that contains the last modification to a master adverse event detail.	ID000000097; ID0000000102; ID000000098
HUM_RSR_AE_ID_MASTER	Human Research Adverse Event Master Identification Code	Character	20	ERESDW1	HUM_RSR_AE_DETAIL	R	A code identifying the human research adverse event detail row that contains the currently approved snapshot of the adverse event detail.	ID000000097; ID0000000102; ID000000098
HUM_RSR_AE_ID_ORIG	Human Research Adverse Event Original Identification Code	Character	20	ERESDW1	HUM_RSR_AE_DETAIL	R	A code identifying the adverse event detail row that contains the original human research adverse event detail.	ID000000097; ID0000000102; ID000000098
HUM_RSR_AE_KEYWORDS	Human Research Adverse Event Keywords Text	Character	256	ERESDW1	HUM_RSR_AE_DETAIL	R	A line of text providing human research adverse events key words.	Headache Multiple Participants; Fainting
HUM_RSR_AE_NAME	Human Research Adverse Event Name	Character	256	ERESDW1	HUM_RSR_AE_ORIO	R	A textual description of an adverse event related to a research study.	HUM00000113_Adverse Event – Fri Jul 1 10:18:45 EDT 2005; B04-00007066-I_Adverse Event – Fri Jul 29 12:42:45 EDT 2005; 2003-0202_Adverse Event – Fri Jul 1 10:18:45 EDT 2005
HUM_RSR_AE_NONSER_UNEXP_REL	Human Research Adverse Event Non Serious Unexpected Relationship	Number	8	ERESDW1	HUM_RSR_AE_DETAIL	R	A number representing the count of non-serious, unexpected, related adverse events for a research study.	0; 5; 47
HUM_RSR_AE_NONSER_UNEXP_UNREL	Human Research Adverse Event Non-Serious, Unexpected, Unrelated Count	Number	8	ERESDW1	HUM_RSR_AE_DETAIL	R	A number representing the count of non-serious, unexpected, unrelated adverse events for a research study.	0; 5; 47
HUM_RSR_AE_NONSER_EXP_REL	Human Research Adverse Event Non-Serious, Expected, Related Count	Number	8	ERESDW1	HUM_RSR_AE_DETAIL	R	A number representing the count of non-serious, expected, related adverse events for a research study.	0; 5; 47

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
HUM_RSR_AE_NONSER_EXP_UNREL	Human Research Adverse Event Non-Serious, Expected, Unrelated Count	Number	8	ERESDW1	HUM_RSR_AE_DETAIL	R	A number representing the count of non-serious, expected, unrelated adverse events for a research study.	0; 5; 47
HUM_RSR_AE_PARENT_PROJECT_ID	Human Research Adverse Event Parent Project Identification Code	Character	20	ERESDW1	HUM_RSR_AE_DETAIL	R	A code identifying a human research adverse event parent project.	HUM000000213; HUM000010003
HUM_RSR_AE_RELATEDNESS	Human Research Adverse Event Relatedness Description	Character	30	ERESDW1	HUM_RSR_AE_DETAIL	R	A textual description of the association of a human research adverse event with the research being conducted.	Unrelated (or not related); Unlikely related; Definitely related
HUM_RSR_AE_REVIEW_TYPE	Human Research Adverse Event Review Type	Character	50	ERESDW1	HUM_RSR_AE_ORIO	R	A code used to identify the type of review conducted for an adverse event related to a research study.	Expedited; Full Committee
HUM_RSR_AE_SEL_FOR_MOD_IND	Human Research Adverse Event Select For Modification Indicator Code	Character	1	ERESDW1	HUM_RSR_AE_DETAIL	R	A code indicating whether a human research adverse event should be selected for modification.	Y = Yes; N = No; null
HUM_RSR_AE_SER_EXP_UNREL	Human Research Adverse Event Serious, Expected, Unrelated Count	Number	8	ERESDW1	HUM_RSR_AE_DETAIL	R	A number representing the count of serious, expected, unrelated adverse events for a research study.	0; 5; 47
HUM_RSR_AE_SER_EXP_REL	Human Research Adverse Event Serious, Expected, Related Count	Number	8	ERESDW1	HUM_RSR_AE_DETAIL	R	A number representing the count of serious, expected, related adverse events for a research study.	0; 5; 47
HUM_RSR_AE_SER_UNEXP_REL	Human Research Adverse Event Serious, Unexpected, Related Count	Number	8	ERESDW1	HUM_RSR_AE_DETAIL	R	A number representing the count of serious, unexpected, related adverse events for a research study.	0; 5; 47
HUM_RSR_AE_SER_UNEXP_UNREL	Human Research Adverse Event Serious, Unexpected, Unrelated Count	Number	8	ERESDW1	HUM_RSR_AE_DETAIL	R	A number representing the count of serious, unexpected, unrelated adverse events for a research study.	0; 5; 47
HUM_RSR_AE_SERIOUS_IND	Human Research Adverse Event Serious Indicator Code	Character	1	ERESDW1	HUM_RSR_AE_DETAIL	R	A code indicating whether a human research adverse event is serious.	Y = Yes; N = No; null

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
HUM_RSR_AE_SEVERITY_GRADE	Human Research Adverse Event Severity Grade Code	Character	100	ERESDW1	HUM_RSR_AE_DETAIL	R	A code indicating how severe a human research adverse event is.	Severe AE (NCI CTC Grade 3); Life-threatening or disabling AE (NCI CTC Grade 4)
HUM_RSR_AE_STATUS	Human Research Adverse Event Status	Character	256	ERESDW1	HUM_RSR_AE_ORIO	R	A textual description used to identify the status of an adverse event for a research study.	Held of Scheduled Continuing Review; Core Committee Staff Review;
HUM_RSR_AE_SUBJ_ID	Human Research Adverse Event Subject Identification Code	Character	20	ERESDW1	HUM_RSR_AE_DETAIL	R	A code identifying the subject of a human research adverse event.	67—97655; 56--00098
HUM_RSR_AE_TYPE	Human Research Adverse Event Type	Character	256	ERESDW1	HUM_RSR_AE_DETAIL HUM_RSR_AE_ORIO	R	A textual description used to identify the type of this adverse event related to a research study.	Adverse event(s) occurring in an unrelated study involving an agent, procedure, or device used in this study; Adverse event involving subjects or others under the oversight of the UM investigator(s) and UM IRB (i.e., performance sites listed in the study)
HUM_RSR_AE_UNIQUE_ID	Human Research Adverse Event Unique Identification Code	Character	20	ERESDW1	HUM_RSR_AE_DETAIL	R	A code assigned by the study team that identifies each human research adverse event. The uniqueness of this field is not enforced by the system.	7899- follow up 11-13-06; 5678
HUM_RSR_AE_VER	Human Research Adverse Event Version Code	Character	20	ERESDW1	HUM_RSR_AE_DETAIL	R	A code identifying the human research adverse event version.	Master; Original; Modification
HUM_RSR_AE_WITHDRAW	Human Research Adverse Event Withdrawal	Number	8	ERESDW1	HUM_RSR_PROJECT HUM_RSR_SCR	R	A number representing a count of withdrawals from a research study due to adverse events.	0; 5; 47
HUM_RSR_AMEND_ID	Human Research Amendment Identification	Character	20	ERESDW1	HUM_RSR_AMEND_REQST_RSN HUM_RSR_AMENDMENT	R	A code uniquely identifying an amendment to a research study.	Ame00000016: Ame00000028

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
HUM_RSR_AMEND_REVIEW_TYPE	Human Research Amendment Review Type	Character	50	ERESDW1	HUM_RSR_AMENDMENT	R	A code used to identify the type of amendment review used for a research study.	Expedited; Full Committee
HUM_RSR_AMEND_STATUS	Human Research Amendment Status	Character	256	ERESDW1	HUM_RSR_AMENDMENT	R	A textual description of the amendment status for a research project.	Pre Submission; Core Committee Staff Review; Approved
HUM_RSR_ANCLRY_COMMITTEE	Human Research Ancillary Committee	Character	30	ERESDW1	HUM_RSR_ANCLRY_COMMITTEE	R	A code representing an ancillary committee related to a research study (there can be more than one).	RPC; SHUR; TPC
HUM_RSR_APPL_TYPE_DESCR256	Human Research Application Type Description	Character	256	ERESDW1	HUM_RSR_PROJECT	R	A textual description of the code representing the type of application submitted for a specific research study.	Emergency one-time use of an investigational or unapproved device; Human Use Device (HUD); Projects lacking immediate plans for involvement of human subjects, their data. And/or their specimens
HUM_RSR_APPL_TYPE_CAT	Human Research Application Type Category	Character	20	ERESDW1	HUM_RSR_PROJECT	R	A code representing a high level grouping of application type submitted for a specific research study.	Special; Standard
HUM_RSR_APPL_TYPE_CD	Human Research Application Type Code	Character	30	ERESDW1	HUM_RSR_PROJECT	R	A code representing the type of application submitted for a specific research study.	Emergency use device; Umbrella; Standard
HUM_RSR_APPROVAL_DT	Human Research Approval Date	Date		ERESDW1	HUM_RSR_PROJECT HUM_RSR_SCR	R	The date on which the human research project was approved.	03/29/2005; 04/14/2005; 05/05/2005
HUM_RSR_COMPLAINT	Human Research Complaint Count	Number	8	ERESDW1	HUM_RSR_PROJECT HUM_RSR_SCR	R	A number representing the count of complaints related to a research study.	0; 1
HUM_RSR_CORE_COMMITTEE_NAME	Human Research Core Committee Name	Character	256	ERESDW1	HUM_RSR_MEETING	R	A textual description of the code representing a core committee related to a research study (there can be more than one).	CPC PRC; GCRC; IRBMED B1

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
HUM_RSR_DEVIATION	Human Research Deviation Count	Number	8	ERESDW1	HUM_RSR_PROJECT HUM_RSR_SCR	R	A number representing the count of deviations used in a research study.	0; 1
HUM_RSR_DEVICE_COMPANY_IND	Human Research Device Company Indicator Code	Character	1	ERESDW1	HUM_RSR_DEVICE	R	A code indicating whether the company which manufactures a device holds the IDE (Investigation Device Tracking Number) for a device used in a research study as a part of the protocol.	Y = Yes; N = No; null
HUM_RSR_DEVICE_COMPANY_NAME	Human Research Device Company Name	Character	256	ERESDW1	HUM_RSR_DEVICE	R	The textual description of the company which manufactures a device used as a part of the protocol for a specific research study.	American Medical Systems; DENTATUS INTERNATIONAL AB; TSL
HUM_RSR_DEVICE_IDE_NUMBER	Human Research Device Investigational Device Tracking Number	Character	256	ERESDW1	HUM_RSR_DEVICE	R	A number which uniquely identifies the FDA (Food and Drug Administration) IDE (Investigation Device Tracking Number) of a device used as part of the protocol for a research study.	99999; G000080; K040143
HUM_RSR_DEVICE_NAME	Human Research Device Name	Character	4000	ERESDW1	HUM_RSR_DEVICE	R	A textual description of a device used in the protocol for a research study.	Bipolar BICAP hemostasis probes (Model BP-7300A, ConMed Corporation); Actigraph light and movement watch
HUM_RSR_DEVICE_OTHER_IND	Human Research Device Other Indicator Code	Character	1	ERESDW1	HUM_RSR_DEVICE	R	A code indicating an organization other than the U of M investigator holds the IDE (Investigation Device Tracking Number) for a device used as part of the protocol for a research study.	Y = Yes; N = No; null
HUM_RSR_DEVICE_OTHER_NAME	Human Research Device Other Name	Character	256	ERESDW1	HUM_RSR_DEVICE	R	A textual description of an organization other than the U of M investigator that holds the IDE (Investigation Device Tracking Number) for a device used as part of the protocol for a research study.	Smith Company
HUM_RSR_DEVICE_UMPI_FIRST_NAME	Human Research Drug U of M Principal Investigator First Name	Character	30	ERESDW1	HUM_RSR_DEVICE	R	The first name of a U of M principal investigator that holds the IDE (Investigation Device Tracking Number) for a device used as part of the protocol for a research study.	Adele; Mason; Supriya

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
HUM_RSR_DEVICE_UMPI_LAST_NAME	Human Research Drug U of M Principal Investigator Last Name	Character	30	ERESDW1	HUM_RSR_DEVICE	R	The last name of a U of M principal investigator that holds the IDE (Investigation Device Tracking Number) for a device used as part of the protocol for a research study.	Banerjee; Samant; Sarter
HUM_RSR_DEVICE_UMPI_PERSON_ID	Human Research Drug U of M Principal Investigator Person Identifier	Character	20	ERESDW1	HUM_RSR_DEVICE	R	A code used to identify a U of M principal investigator who holds the IDE (Investigation Device Tracking Number) for a device used as part of the protocol for a research study.	05881664; 10857334; 21144886
HUM_RSR_DEVICE_UMPI_IND	Human Research Device U of M Principal Investigator Indicator Code	Character	1	ERESDW1	HUM_RSR_DEVICE	R	A code indicating whether a U of M principal investigator holds the IDE (Investigation Device Tracking Number) for a device used as part of the protocol for a research study.	Y = Yes; N = No; null
HUM_RSR_DRUG_ARTICLE_TYPE	Human Research Drug Article Type	Character	256	ERESDW1	HUM_RSR_DRUG	R	A textual description of a drug article used in a research study.	Drug/biological; Gas; Other Material
HUM_RSR_DRUG_COMPANY_IND	Human Research Drug Company Indicator Code	Character	1	ERESDW1	HUM_RSR_DRUG	R	A code indicating whether a company holds the IND (Investigational New Drug) for a drug used as part of the protocol for a research study.	Y = Yes; N = No; null
HUM_RSR_DRUG_COMPANY_NAME	Human Research Drug Company Name	Character	256	ERESDW1	HUM_RSR_DRUG	R	A textual description of the company who holds the IND (Investigational New Drug) for a drug used as part of the protocol for a research study.	3M Pharmaceutical; Amgen, Inc.; CTEP
HUM_RSR_DRUG_IND_NUMBER	Human Research Drug Investigational New Drug Number	Character	256	ERESDW1	HUM_RSR_DRUG	R	The FDA (Food and Drug Administration) IND (Investigational Drug Tracking Number) for a drug used as part of the protocol for a research study.	64609; 71388; IND # 70274
HUM_RSR_DRUG_NAME	Human Research Drug Name	Character	4000	ERESDW1	HUM_RSR_DRUG	R	A textual description of a drug used as part of the protocol for a research study.	Azithromycin; Basiliximab; Cetuximab
HUM_RSR_DRUG_OTHER_NAME	Human Research Drug Other Name	Character	256	ERESDW1	HUM_RSR_DRUG	R	A textual description of an organization other than a U of M investigator which holds the IND (Investigational Drug Tracking Number) for a drug used as part of the protocol for a research study.	NCI Division of Cancer Prevention; Smith Organization

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
HUM_RSR_DRUG_OTHER_IND	Human Research Drug Other Indicator Code	Character	1	ERESDW1	HUM_RSR_DRUG	R	A code indicating whether an organization other than a U of M investigator holds the IND (Investigational Drug Tracking Number) for a drug used as part of the protocol for a research study.	Y = Yes; N = No; null
HUM_RSR_DRUG_UMPI_FIRST_NAME	Human Research Drug U of M Principal Investigator First Name	Character	30	ERESDW1	HUM_RSR_DRUG	R	The first name of a U of M principal investigator that holds the IND (Investigational Drug Tracking Number) for a drug used as a part of the protocol for a research study.	Adele; Mason; Supriya
HUM_RSR_DRUG_UMPI_LAST_NAME	Human Research Drug U of M Principal Investigator Last Name	Character	30	ERESDW1	HUM_RSR_DRUG	R	The last name of a U of M principal investigator that holds the IND (Investigational Drug Tracking Number) for a drug used as part of the protocol for a research study.	Banerjee; Samant; Sarter
HUM_RSR_DRUG_UMPI_PERSON_ID	Human Research Drug U of M Principal Investigator Person Identifier	Character	20	ERESDW1	HUM_RSR_DRUG	R	A code used to identify a U of M principal investigator who holds the IND (Investigational Drug Tracking Number) for a drug used as part of the protocol for a research study.	05881664; 10857334; 21144886
HUM_RSR_DRUG_UMPI_IND	Human Research Drug U of M Principal Investigator Indicator Code	Character	1	ERESDW1	HUM_RSR_DRUG	R	A code indicating a U of M principal investigator holds the IND (Investigational Drug Tracking Number) for a drug used as part of the protocol for a research study.	Y = Yes; N = No; null
HUM_RSR_END_DT	Human Research End Date	Date		ERESDW1	HUM_RSR_PROJECT	R	The estimated date that a research study should end.	03/29/2005; 04/14/2005; 05/05/2005
HUM_RSR_EXPIRE_DT	Human Research Expiration Date	Date		ERESDW1	HUM_RSR_PROJECT HUM_RSR_SCR	R	The date on which the IRB (Institutional Review Board) approval for a research study expires.	03/29/2005; 04/14/2005; 05/05/2005
HUM_RSR_FINANCIAL_SPON_TYPE	Human Research Financial Sponsor Type Code	Character	15	ERESDW1	HUM_RSR_EXT_SPONSOR HUM_RSR_INT_SPONSOR	R	A code used to identify the type of sponsorship a sponsor is providing for a research study.	Both Financial; Financial; Non-financial
HUM_RSR_INITIAL_APPROVAL_DT	Human Research Initial Approval Date	Date		ERESDW1	HUM_RSR_PROJECT	R	The date on which a research study is initially approved by the IRB (Institutional Review Board).	03/29/2005; 04/14/2005; 05/05/2005

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
HUM_RSR_INITIATOR	Human Research Initiator	Character	256	ERESDW1	HUM_RSR_PROJECT	R	A textual description of the initiator of a specific research study.	Industry; Investigator; National cooperative group (clinical)
HUM_RSR_IRB_ADDRESS	Human Research Institutional Review Board Address	Character	256	ERESDW1	HUM_RSR_IRB	R	The address of the institutional review board overseeing a research study.	4901 Evergreen Rd., 118 SB, Dearborn, MI 48128;  540 East Liberty Street, Suite 202, Ann Arbor, MI 48104-2210
HUM_RSR_IRB_CORE_STAFF	Human Research Institutional Review Board Core Staff	Character	256	ERESDW1	HUM_RSR_IRB	R	The textual description of a core staff member of an institutional review board.	IRB Dearborn; IRB Flint; IRB MED
HUM_RSR_IRB_DESCR256	Human Research Institutional Review Board Description	Character	256	ERESDW1	HUM_RSR_IRB	R	A textual description of the short name for a particular institutional review board.	Dearborn Institutional Review Board (IRB); Flint Institutional Review Board (IRB); Health Sciences Institutional Review Board (IRB)
HUM_RSR_IRB_EMAIL	Human Research Institutional Review Board Email	Character	256	ERESDW1	HUM_RSR_IRB	R	The electronic mail address of a particular institutional review board.	Irbdearborn@umd.umich.edu; research@umflint.edu; <a href="mailto:irbmed@umich.edu">irbmed@umich.edu</a>
HUM_RSR_IRB_FAX	Human Research Institutional Review Board FAX	Character	256	ERESDW1	HUM_RSR_IRB	R	The fax telephone number of a particular institutional review board.	(313)593-0526; (734)998-9171; (734)763-9603
HUM_RSR_IRB_LONGNAME	Human Research Institutional Review Board Long Name	Character	256	ERESDW1	HUM_RSR_IRB	R	The full name by which the institutional review board is known.	Dearborn Institutional Review Board (IRB); Flint Institutional Review Board (IRB); Health Sciences Institutional Review Board (IRB)

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
HUM_RSR_IRB_NAME	Human Research Institutional Review Board Name	Character	50	ERESDW1	HUM_RSR_IRB HUM_RSR_PROJECT	R	The abbreviated name for a particular institutional review board.	Dearborn; Flint; IRBMED
HUM_RSR_IRB_PHONE	Human Research Institutional Review Board Phone Number	Character	256	ERESDW1	HUM_RSR_IRB	R	The telephone number of a particular institutional review board.	(810)762-3383; (734)936-0933; (313)593-5468
HUM_RSR_IRB_WEB_ADDRESS	Human Research Institutional Review Board Web Address	Character	256	ERESDW1	HUM_RSR_IRB	R	The electronic web address of a particular institutional review board.	<a href="http://research.umflint.edu/web/human_subjects.htm">http://research.umflint.edu/web/human_subjects.htm</a> ; <a href="http://www.med.umich.edu/irbmed">http://www.med.umich.edu/irbmed</a>
HUM_RSR_KIND_OF_SPECIMEN	Human Research Kind of Specimen Text	Character	4000	ERESDW1	HUM_RSR_PROJECT_DETAIL	R	A textual description of the classification of a human research specimen.	Urine; Saliva
HUM_RSR_LOCATION	Human Research Location Text	Character	256	ERESDW1	HUM_RSR_PROJ_FUNCTION HUM_RSR_PROJ_LOCATION	R	A textual description of the location where research will be conducted.	University of Michigan; Elementary School
HUM_RSR_LOCATION_ENGAGED_IND	Human Research Location Engaged Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJ_LOCATION	R	A code indicating whether a human subject research location is being utilized for the research.	Y = Yes; N = No; null
HUM_RSR_MEETING_DT	Human Research Meeting Date	Date		ERESDW1	HUM_RSR_MEETING	R	The date on which a core committee (IRB, GCRC, or PRC) meeting is held.	03/29/2005; 04/14/2005; 05/05/2005
HUM_RSR_MEETING_END_TIME	Human Research Meeting End Time	Time		ERESDW1	HUM_RSR_MEETING	R	The time at which a core committee (IRB, GCRC, or PRC) meeting is ended.	03/29/2005 3:00 pm
HUM_RSR_MEETING_ID	Human Research Meeting Identification	Character	20	ERESDW1	HUM_RSR_MEETING HUM_RSR_MEETING_AGENDA	R	A code used to uniquely identify a core committee (IRB, GCRC, or PRC) associated with a meeting.	Mee00000002; Mee00000033; Mee00000076
HUM_RSR_MEETING_START_TIME	Human Research Start Time	Time		ERESDW1	HUM_RSR_MEETING	R	The time at which a core committee (IRB, GCRC, or PRC) meeting is scheduled to begin.	03/29/2005 3:00 pm
HUM_RSR_MOD_PROJECT_ID	Human Research Modified Project Identification	Character	20	ERESDW1	HUM_RSR_AMENDMENT	R	A code used to identify a modified research study.	HUM00000131; HUM00000203; HUM00000358

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
HUM_RSR_NO_SPONSOR_IND	Human Research No Sponsor Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether a specific research study has no sponsor.	Y = Yes; N = No; null
HUM_RSR_ORIG_PROJECT_ID	Human Research Original Project Identification	Character	20	ERESDW1	HUM_RSR_PROJECT	R	A code uniquely identifying the initial (unmodified) research study.	HUM00000237; HUM00001032; HUM00001321
HUM_RSR_OTHER_FUNCTION_TYPE	Human Research Other Function Type Text	Character	256	ERESDW1	HUM_RSR_PROJ_LOCATION	R	A textual description of the other type of work that will be completed at a research location.	One Site in Multi-Center Project; Sole Site
HUM_RSR_PARENT_PROJECT_ID	Human Research Parent Project Identification	Character	20	ERESDW1	HUM_RSR_AE_ORIO HUM_RSR_AMENDMENT HUM_RSR_SCR	R	A code uniquely identifying the initial (unmodified) research study.	B04-00007065-I; H04-00004278-R1; HUM00001887
HUM_RSR_PROJ_FUNCTION_TYPE	Human Research Project Function Type Code	Character	100	ERESDW1	HUM_RSR_PROJ_FUNCTION	R	A code identifying the type of human research project function.	Intervention; Storage; Interaction; Analysis; Recruitment

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
HUM_RSR_PROJECT_ID	Human Research Project Identification	Character	20	ERESDW1	HUM_RSR_ANCLRY_COMMITTEE HUM_RSR_CNST_DOC_WVR_TYP HUM_RSR_CNST_WVR_TYP HUM_RSR_CONSENT_TYP HUM_RSR_CORE_COMMITTEE HUM_RSR_DEVICE HUM_RSR_DRUG HUM_RSR_EXT_SPONSOR HUM_RSR_INT_SPONSOR HUM_RSR_PROJECT HUM_RSR_PROJ_COMP HUM_RSR_PROJECT_DETAIL HUM_RSR_PROJ_LOCATION HUM_RSR_PROJ_SUBJ_COST HUM_RSR_RISK_LVL_HISTORY HUM_RSR_STUDY_TEAM HUM_RSR_UM_PROJ_FACILITY HUM_RSR_PROJ_FUNCTION	R	A code uniquely identifying a research project.	2002-0392; B03-00000453-R2
HUM_RSR_PROJECT_STATUS	Human Research Project Status	Character	256	ERESDW1	HUM_RSR_PROJECT	R	A textual description of the research project status.	Approved; Complete Application; Change Required By Core Staff
HUM_RSR_PRSN_SECRTY_ROLE	Human Research Person Security Role	Character	30	ERESDW1	HUM_RSR_PRSN_SECRTY_ROLE	R	A code representing a person's security role in the human research system.	BEU; COI Med; Exempt Reviewer
HUM_RSR_PUBLICATION	Human Research Publication Count	Number	8	ERESDW1	HUM_RSR_PROJECT HUM_RSR_SCR	R	A number representing the count of publications submitted as a part of a research study.	0; 5; 6
HUM_RSR_RECOMMENDED_MOTION	Human Research Recommended Motion Code	Character	40	ERESDW1	HUM_RSR_SUBMSSION_REVIEW	R	A code indicating the recommended motion for a human research submission.	Approved; Action Deferred to Study Team

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
HUM_RSR_REVIEW_CREATE_DT	Human Research Review Create Date	Date		ERESDW1	HUM_RSR_SUBMSSION_REVIEW	R	The date on which a human research submission for review was created.	12/20/2006; 2/1/2007
HUM_RSR_REVIEW_STATUS	Human Research Review Status Description	Character	256	ERESDW1	HUM_RSR_SUBMSSION_REVIEW	R	A textual description of the status of a human research submission review.	Initial Review; Submitted
HUM_RSR_REVIEW_TYPE	Human Research Review Type	Character	50	ERESDW1	HUM_RSR_SCR	R	A code used to identify the type of review used for a research study.	Expedited; Full Committee
HUM_RSR_REVIEWER_COMMITTEE	Human Research Reviewer Committee Name	Character	30	ERESDW1	HUM_RSR_SUBMSSION_REVIEW	R	The name of the committee that the human research submission review is associated with.	IRBMED A1; IRB Behavioral Science; PRC; GCRC
HUM_RSR_REVIEWER_PERSON_ID	Human Research Reviewer Person Identification	Character	20	ERESDW1	HUM_RSR_SUBMSSION_REVIEW	R	An identification code used in the human research system to identify the reviewer for the submission related to a research study. If the person is a U of M staff member this will be their EMPLID.	12345678
HUM_RSR_REVIEWER_FIRST_NAME	Human Research Reviewer First Name	Character	30	ERESDW1	HUM_RSR_SUBMSSION_REVIEW	R	The first name of the assigned human research submission reviewer.	John
HUM_RSR_REVIEWER_LAST_NAME	Human Research Reviewer Last Name	Character	30	ERESDW1	HUM_RSR_SUBMSSION_REVIEW	R	The last name of the assigned human research submission reviewer.	Doe
HUM_RSR_REVIEWER_ROLE	Human Research Reviewer Role Code	Character	50	ERESDW1	HUM_RSR_SUBMSSION_REVIEW	R	A code indicating the role a reviewer has in a human research submission review.	IRB = Primary Reviewer; GCRC = Secondary Reviewer; PRC = Statistical Reviewer
HUM_RSR_RISK_LVL	Human Research Risk Level	Character	50	ERESDW1	HUM_RSR_PROJECT HUM_RSR_RISK_LVL_HISTORY HUM_RSR_SCR	R	A code representing the level of risk associated with a research study.	High risk; Minor increase over minimal risk; No more than minimal risk
HUM_RSR_SCR_ID	Human Research Scheduled Continuing Review Identification	Character	20	ERESDW1	HUM_RSR_SCR	R	A code identifying the scheduled continuing review of a research study.	CR00000006; CR00000018

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
HUM_RSR_SCR_STATUS	Human Research Scheduled Continuing Review Status	Character	256	ERESDW1	HUM_RSR_SCR	R	A textual description of a status of the scheduled continuing review of a research study.	Pre Submission; Core Committee Staff Review; Approved
HUM_RSR_SCR_STDY_STAT_CD	Human Research Scheduled Continuing Review Study Status Code	Character	30	ERESDW1	HUM_RSR_SCR	R	A code representing the status of a study related to the continual review scheduled for a research study.	Analysis identifiable data; Active with subjects; Analysis de-identified data
HUM_RSR_SCR_STDY_STAT_DESCR256	Human Research Scheduled Continuing Review Study Status Description	Character	256	ERESDW1	HUM_RSR_SCR	R	A textual description of code representing the status of a study related to the continual review scheduled for a research study.	All intervention/interaction w; The study is completed; there
HUM_RSR_SPECIMEN_CLLCTN_SCHED	Human Research Specimen Collection Schedule Text	Character	4000	ERESDW1	HUM_RSR_PROJECT_DETAIL	R	A textual description of the schedule established for the collection of human research specimens.	Monthly; Weekly during examination
HUM_RSR_SPONSOR_NOTES	Human Research Sponsor Notes	Character	4000	ERESDW1	HUM_RSR_EXT_SPONSOR	R	The sponsor notes related to a research study. This information is applicable only for converted IRBM studies.	Sponsor requires an update weekly.
HUM_RSR_SSP_NUMBER	Human Research Specialized Service Proposal Number	Character	256	ERESDW1	HUM_RSR_EXT_SPONSOR	R	The Specialized Service Proposal number assigned to non-financial sponsorship by DRDA (Division of Research Development Administration) office.	1; 44; 6311
HUM_RSR_START_DT	Human Research Start Date	Date		ERESDW1	HUM_RSR_PROJECT	R	The date on which a research study is scheduled to start.	03/29/2005; 04/14/2005; 05/05/2005
HUM_RSR_STATUS_METER	Human Research Status Meter	Character	50	ERESDW1	HUM_RSR_AE_ORIO HUM_RSR_PROJECT HUM_RSR_SCR	R	A code representing a status meter used to show a high level workflow status of the submission review. Abbreviated values are used for AE-ORIO and SCR submission that only require IRB review.	Abbreviated Withdrawn; Ancillary Review

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
HUM_RSR_STUDY_FULL_TITLE	Human Research Study Full Title	Character	4000	ERESDW1	HUM_RSR_PROJECT	R	The full title of a research study.	131 I-MIBG therapy for refractory neuroblastoma – single patient use; Reducing Health Disparities in Childhood Obesity
HUM_RSR_STUDY_TITLE	Human Research Study Title	Character	256	ERESDW1	HUM_RSR_PROJECT	R	The title of a research study.	Effect of Scientific Elite Conflict on Public Opinion; Peer facilitation of community service learning; Qualitative description of women and spirituality group
HUM_RSR_STUDY_TM_MEM_ID	Human Research Study Team Member Identification	Character	20	ERESDW1	HUM_RSR_STUDY_TEAM	R	A code identifying a study team member related to a research study.	0021662; 00352442; 00386639
HUM_RSR_STUDY_TM_MEM_ROLE	Human Research Study Team Member Role	Character	50	ERESDW1	HUM_RSR_STUDY_TEAM	R	A code indicating the role of a study team member on a research study.	Other; Co-Investigator; Staff
HUM_RSR_SUBJ_AGE_MAX	Human Research Subject Age Maximum	Number	5,2	ERESDW1	HUM_RSR_PROJECT	R	A number representing the maximum human research subject age for a specific research study.	0.5; 5; 17; 55; 999
HUM_RSR_SUBJ_AGE_MIN	Human Research Subject Age Minimum	Number	5,2	ERESDW1	HUM_RSR_PROJECT	R	A number representing the minimum human research subject age for a specific research study.	0.5; 5; 17; 55; 999
HUM_RSR_SUBJ_EXISTING_DATA	Human Research Subject Existing Data Count	Number	8	ERESDW1	HUM_RSR_PROJECT	R	A number representing the count of the subjects that are represented in existing data used in the research study.	14; 999; 29686812

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
HUM_RSR_SUBJ_TOT	Human Research Subject Total Count	Number	8	ERESDW1	HUM_RSR_PROJECT	R	A number representing the total count of subjects participating in a research study.	15; 529; 999999
HUM_RSR_SUBMISSION_REV_ID	Human Research Submission Review Identification Code	Character	20	ERESDW1	HUM_RSR_SUBMSSION_REVIEW	R	A code identifying a particular human research submission review.	HUM00000001; ADV00000001; AME00000001; CR00000001
HUM_RSR_SUBMISSION_REV_NAME	Human Research Submission Review Name	Character	256	ERESDW1	HUM_RSR_SUBMSSION_REVIEW	R	The name of a particular human research submission review.	Staff Review for HUM0000126; Expedited Review for HUM0000126
HUM_RSR_SUBMISSION_REV_TYPE	Human Research Submission Review Type Code	Character	50	ERESDW1	HUM_RSR_SUBMSSION_REVIEW	R	A code used to identify the type of human research submission.	Protocol; Adverse Event; Amendments
HUM_RSR_SUBMISSION_NAME	Human Research Submission Name	Character	256	ERESDW1	HUM_RSR_STATE_TRANSITION	R	A textual description of the code uniquely identifying a submission in the human research system. A submission can be a project, scheduled continuing review, an amendment, an adverse event or other reportable incident on a meeting agenda.	Making a Case for New Elementary Science Teachers; Contingencies of self-worth and self-schemas; Women, Minorities and Technology
HUM_RSR_SUBMISSION_STATUS	Human Research Submission Status	Character	256	ERESDW1	HUM_RSR_STATE_TRANSITION	R	A textual description of the status of a submission.	Approved; Complete Application; Disapproved
HUM_RSR_SUBMISSION_TYPE	Human Research Submission Type	Character	30	ERESDW1	HUM_RSR_AE_ORIO HUM_RSR_AMENDMENT HUM_RSR_MEETING_AGENDA HUM_RSR_PROJECT HUM_RSR_SCR HUM_RSR_STATE_TRANSITION	R	A code used to identify the type of submission.	_Protocol; Adverse Event; Amendments
HUM_RSR_SUBMISSION_DT	Human Research Submission Date	Date		ERESDW1	HUM_RSR_PROJECT	R	The date that the project was submitted for review.	12/20/2006; 2/1/2007

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
HUM_RSR_SUBMISSION_ID	Human Research Submission Identification	Character	20	ERESDW1	HUM_RSR_MEETING_AGENDA HUM_RSR_STATE_TRANSITION HUM_RSR_SUBMISSION_REVIEW	R	A code uniquely identifying a submission in the human research system. A submission can be a project, scheduled continuing review, an amendment, an adverse event or other reportable incident on a meeting agenda.	2003-0202; 2004-0381; B03-00000422-R2
HUM_RSR_UM_FACILITY	Human Research University of Michigan Facility Description	Character	60	ERESDW1	HUM_RSR_UM_PROJ_FACILITY	R	A textual description of the U of M facility where research will be conducted.	University Hospital; Taubman Center Clinics
IDS_HOME_CARE_SERVICES_IND	Investigational Drug Service Home Care Services Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT_DETAIL	R	A code indicating whether investigational drug services home care services will be required for a human subject research project.	Y = Yes; N = No; null
IN_VITRO_FERTIL_IND	In Vitro Fertilization Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether in vitro fertilization is part of a specific research study.	Y = Yes; N = No; null
INFORM_CONSENT_CHG_REQRED_IND	Informed Consent Change Required Indicator Code	Character	1	ERESDW1	HUM_RSR_AMENDMENT	R	A code indicating whether a change has been requested to the requirement for informed consent for a research study.	Y = Yes; N = No; null
INTERNATIONAL_IND	International Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether a specific research study project is international or not.	Y = Yes; N = No; null
INTERNET_IND	Internet Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether a specific research study project is internet based or not.	Y = Yes; N = No; null
IONIZING_RADIATION_IND	Ionizing Radiation Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether ionizing radiation is a part of a specific research study.	Y = Yes; N = No; null
IRB_RECEIPT_DT	Institutional Review Board Receipt Date	Date		ERESDW1	HUM_RSR_AE_ORIO HUM_RSR_AMENDMENT HUM_RSR_PROJECT HUM_RSR_SCR	R	The date that a submission was received by the IRB (Institutional Review Board).	03/29/2005; 04/14/2005; 05/05/2005

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
LACTATING_IND	Lactating Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether lactating women are part of a specific research study.	Y = Yes; N = No; null
LAST_AMEND_APPROVAL_DT	Last Amendment Approval Date	Date		ERESDW1	HUM_RSR_PROJECT	R	The date on which the last amendment was approved for a research study.	03/29/2005; 04/14/2005; 05/05/2005
LAST_SCR_APPROVAL_DT	Last Scheduled Continuing Review Approval Date	Date		ERESDW1	HUM_RSR_PROJECT	R	The date on which the last scheduled continuing review for a research study was approved.	03/29/2005; 04/14/2005; 05/05/2005
LAST_SCR_INELIGIBLE_SCREEN	Last Scheduled Continuing Review Ineligible Screening Count	Number	8	ERESDW1	HUM_RSR_SCR	R	A number representing the count of ineligible screenings that occurred since the last scheduled continuing review for a research study.	10; 223; 16000
LAST_SCR_SCREEN_INELIG_TOT	Last Scheduled Continuing Review Screen Ineligible Total Count	Number	8	ERESDW1	HUM_RSR_PROJECT	R	A number representing the total count of ineligible screenings for a research study.	147; 263; 400
LAST_SCR_SUBJ_DATA	Last Scheduled Continuing Review Subject Data Count	Number	8	ERESDW1	HUM_RSR_SCR	R	A number representing the count of subjects for which data was collected since the last scheduled continuing review for a research study.	35; 600; 48000
LAST_SCR_SUBJ_DATA_TOT	Last Scheduled Continuing Review Subject Data Total Count	Number	8	ERESDW1	HUM_RSR_PROJECT	R	A number representing the total count of subjects for which data was collected for a research study.	20; 846; 50000
LAST_SCR_SUBJ_ENROLLED	Last Scheduled Continuing Review Subject Enrolled Count	Number	8	ERESDW1	HUM_RSR_PROJECT	R	A number representing the count of subjects enrolled since the last scheduled continuing review for a research study.	15; 232; 27109
LAST_SCR_WITHDRAW	Last Scheduled Continuing Review Withdrawal Count	Number	8	ERESDW1	HUM_RSR_SCR	R	A number representing the count of subject withdrawals since the last scheduled continuing review for a research study.	0; 53
LAST_SCR_WITHDRAW_TOT	Last Scheduled Continuing Review Withdrawal Total Count	Number	8	ERESDW1	HUM_RSR_PROJECT	R	A number representing the total count of subject withdrawals for a research study.	0; 53; 666

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
LOAD_DT	Load Date	Date		ERESDW1	HUM_RSR_STATUS	R	The date and time at which the data was loaded into the data warehouse. This data may have been loaded into a single table, a group of tables or an entire dataset, as designated by the information provided in the field DW_DATA.	08/4/2000 11:40:13 AM
LOGIN_ID	Login Identification	Character	100	ERESDW1	RESEARCH_PROJECT_PERSON	R	The person's login id for the human research system. If the person is a U of M staff member this will be their unickname.	Aalzoubi; Claire.Robinson@med.va.gov; Johnjie1@yahoo.com
MILLISECONDS_IN_STATE	Milliseconds In State	Number	38	ERESDW1	HUM_RSR_STATE_TRANSITION	R	The number of milliseconds a submission remained in a particular state within the system.	33,000; 35,000; 43,000
NAME	Name	Character	50	ERESDW1	RESEARCH_PROJECT_PERSON	R	The name by which a person is known. Person name format is Last,First Middle.	de la Garza, Barbara Marie; Smith, Joseph L; Washington, William Boyd
NEW_STATE	New State	Character	256	ERESDW1	HUM_RSR_STATE_TRANSITION	R	A textual description of the new state a submission entered into.	Approved; Core Committee Staff Review; Changes Required By Core Staff
NON_VIABLE_NEONATES_IND	Non-Viable Neonates Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether non viable neonates are part of a specific research study.	Y = Yes; N = No; null
OLD_STATE	Old State	Character	256	ERESDW1	HUM_RSR_STATE_TRANSITION	R	A textual description of the state a submission left when it entered into a new state. Use this attribute to identify the state for any calculation using milliseconds in state.	Disapproved; Expired; Initial
ORGAN_TISSUE_TRNSFR_IND	Organ Tissue Transfer Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether organ tissue transfer is a part of a specific research study.	Y = Yes; N = No; null

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
OTH_BILL_SPONSOR_NAME	Other Billing Sponsor Name	Character	256	ERESDW1	HUM_RSR_EXT_SPONSOR HUM_RSR_INT_SPONSOR	R	The name by which a billing sponsor not listed in the sponsor table of a research study is known.	P336C2001504A; Serono, Inc.; US EPA Leland
OTH_SPONSOR_NAME	Other Sponsor Name	Character	256	ERESDW1	HUM_RSR_EXT_SPONSOR	R	The name by which the sponsor not listed in the sponsor table of a research study is known.	Georgetown University; NASA – Ames Research Center; University of Alabama at Birmingham
OTH_SPONSOR_TYPE	Other Sponsor Type	Character	100	ERESDW1	HUM_RSR_EXT_SPONSOR	R	A description used by the U of M to identify the type of a sponsor that is not listed in the sponsor table.	National (non-federal)organization: NIH; Renal Research Institute, LLC
OWNER_FIRST_NAME	Owner First Name	Character	30	ERESDW1	HUM_RSR_AE_ORIO HUM_RSR_PROJECT HUM_RSR_SCR	R	The first name of the processing staff owner for the submission related to a research study.	Adele; Mason; Supriya
OWNER_LAST_NAME	Owner Last Name	Character	30	ERESDW1	HUM_RSR_AE_ORIO HUM_RSR_PROJECT HUM_RSR_SCR	R	The last name of the processing staff owner for the submission related to a research study.	Banerjee; Samant; Sarter
OWNER_PERSON_ID	Owner Person Identifier	Character	20	ERESDW1	HUM_RSR_AE_ORIO HUM_RSR_PROJECT HUM_RSR_SCR	R	An identification code used in the human research system to identify the processing staff owner for the submission related to a research study. If the person is a U of M staff member this will be their EMPLID.	05881664; 10857334; 21144886
PERSON_EMAIL	Person Email	Character	100	ERESDW1	RESEARCH_PROJECT_PERSON	R	The electronic mail address of a particular person.	johndoe@umich.edu
PERSON_FIRST_NAME	Person First Name	Character	30	ERESDW1	RESEARCH_PROJECT_PERSON	R	The first name part of a person's name.	Adele; Mason; Supriya
PERSON_ID	Person Identification	Character	20	ERESDW1	HUM_RSR_PRSN_SECRTY_ROLE RESEARCH_PROJECT_PERSON	R	A person identification code used in the human research system. If the person is a U of M staff member this will be their EMPLID.	05881664; 10857334; 21144886

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
PERSON_LAST_NAME	Person Last Name	Character	30	ERESDW1	RESEARCH_PROJECT_PERSON	R	The last name part of a person's name.	Banerjee; Samant; Sarter
PERSON_MIDDLE_NAME	Person Middle Name	Character	30	ERESDW1	RESEARCH_PROJECT_PERSON	R	The middle name part of a person's name.	Adams; F; Rosch
PERSON_RSR_DEPT_DESCR	Person Research Department Description	Character	30	ERESDW1	RESEARCH_PROJECT_PERSON	R	A textual description of the code that identifies each academic or administrative unit that has programmatic, operational and fiscal (including budgetary) responsibility for a person involved in research.	Physics Department; College of Lit, Science & Arts; UMH Administration;
PERSON_RSR_DEPTID	Person Research Department Identification Code	Character	10	ERESDW1	RESEARCH_PROJECT_PERSON	R	A code that identifies each academic or administrative unit that has programmatic, operational and fiscal (including budgetary) responsibility for a person involved in research.	184500 = Physics Department; 170000 = College of Lit, Science & Arts; 311679 = UMH Administration
PERSON_UNIQNAME	Person Unique Name	Character	8	ERESDW1	RESEARCH_PROJECT_PERSON	R	A name which is the computing identity of an entity at the University.	Bif; rduff; jsagawa
PI_FIRST_NAME	Principal Investigator First Name	Character	30	ERESDW1	HUM_RSR_PROJECT	R	The first name part of a principal investigator's name.	Abigail; Jina; Naila
PI_LAST_NAME	Principal Investigator Last Name	Character	30	ERESDW1	HUM_RSR_PROJECT	R	The last name part of a principal investigator's name.	Banerjee; Samant; Sarter
PI_MIDDLE_NAME	Principal Investigator Middle Name	Character	30	ERESDW1	HUM_RSR_PROJECT	R	The middle name part of a principal investigator's name.	Adams; F; Rosch
PI_PERSON_ID	Principal Investigator Person Identifier	Character	20	ERESDW1	HUM_RSR_PROJECT	R	A code uniquely identifying a principal investigator.	46431302; 53122550; 98369363

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
PI_UNIQUE_NAME	Principal Investigator Unique Name	Character	8	ERESDW1	HUM_RSR_PROJECT	R	A name which is the computing identity of a principal investigator at the U of M.	ssamant; mbeleh; wongn
PLACEBO_IND	Placebo Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether a placebo is used as a part of a specific research study.	Y = Yes; N = No; null
PRC_APPROVAL_DT	Protocol Review Committee Approval Date	Date		ERESDW1	HUM_RSR_AMENDMENT HUM_RSR_PROJECT	R	The date that the submission was approved by the Cancer Center Protocol Review Committee.	03/29/2005; 04/14/2005; 05/05/2005
PRC_ID	Protocol Review Committee Identification	Character	256	ERESDW1	HUM_RSR_PROJECT	R	A code identifying a Cancer Center Protocol Review Committee tracking number used for a research study. This information is applicable only for converted IRBMED (Institutional Review Board MED) study.	9219; 9507
PRC_RECEIPT_DT	Protocol Review Committee Receipt Date	Date		ERESDW1	HUM_RSR_AMENDMENT HUM_RSR_PROJECT	R	The date that the submission was received by the Cancer Center Protocol Review Committee.	03/29/2005; 04/14/2005; 05/05/2005
PREGNANT_FETUS_IND	Pregnant or Fetus Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether pregnant women or fetuses are part of a specific research study.	Y = Yes; N = No; null
PRIMARY_FIRST_NAME	Primary First Name	Character	30	ERESDW1	RESEARCH_PROJECT_PERSON	R	The legal first name of a specified person for a specific research project.	George; Bob; Maynard
PRIMARY_LAST_NAME	Primary Last Name	Character	30	ERESDW1	RESEARCH_PROJECT_PERSON	R	The legal last name of a specified person for a specific research project.	Smith; James; Williams
PRIMARY_MIDDLE_NAME	Primary Middle Name	Character	30	ERESDW1	RESEARCH_PROJECT_PERSON	R	The legal middle name of a specified person for a specific research project.	Jessica; Michelle David
PRIMARY_NAME	Primary Name	Character	50	ERESDW1	RESEARCH_PROJECT_PERSON	R	The legal full name of a specified person for a specific research project.	Billy Bob Thornton; Andrew Lloyd Webber; Sarah Michelle Gellar
PRISONER_IND	Prisoner Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether prisoners are part of a specific research study.	Y = Yes; N = No; null

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
RISK_LVL_CHG_IND	Risk Level Change Indicator Code	Character	1	ERESDW1	HUM_RSR_AMENDMENT	R	A code indicating whether a change in risk level is part of a research amendment.	Y = Yes; N = No; null
RISK_LVL_DIRECT_BEN	Risk Level Direct Benefit	Character	4000	ERESDW1	HUM_RSR_PROJECT	R	A textual description of direct benefits from a particular risk level associated with a research study.	1. Enhance student learning   2. Preserve university history;  Academic Learning about the cognitive and affective progress through which advertising shapes brand perception and preference
RISK_LVL_DIRECT_BEN_IND	Risk Level Direct Benefit Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether a risk level brings a direct benefit to a specific research study.	Y = Yes; N = No; null
RISK_LVL_DIRECT_RISK	Risk Level Direct Risk	Character	4000	ERESDW1	HUM_RSR_PROJECT	R	A textual description of direct risk from a particular risk level associated with a research study.	1. Inappropriate disclosure of medical information. We anticipate that this will be rare. No other risk to patient;  1. May encounter vulgar language on the public Usenet list – Infrequent.
RISK_LVL_INDIRECT_BEN	Risk Level Indirect Benefit	Character	4000	ERESDW1	HUM_RSR_PROJECT	R	A textual description of indirect benefits from a particular risk level associated with a research study.	None;  The group visits will serve as a template for other target groups within Chelsea Family Medicine clinic.
RISK_LVL_INDIRECT_BEN_IND	Risk Level Indirect Benefit Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether a risk level brings an indirect benefit to a specific research study.	Y = Yes; N = No; null

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
RISK_LVL_INDIRECT_RISK	Risk Level Indirect Risk	Character	4000	ERESDW1	HUM_RSR_PROJECT	R	A textual description of indirect risk from a particular risk level associated with a research study.	Any direct risk to the public or community will not be expected.;  As this study involves only self-reporting information of thoughts and benefits, this study poses no risk to the public
RISK_PREG_WOMEN_FETUS_IND	Risk Pregnant Women Fetus Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT_DETAIL	R	A code indicating whether there is a risk to pregnant women or fetuses from a specific research study.	Y = Yes; N = No; null
SECOND_DATA_ANALYSIS_IND	Second Data Analysis Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether a second data analysis is a part of a specific research study.	Y = Yes; N = No; null
SECONDARY_OWNER_PERSON_ID	Owner Person Identifier	Character	20	ERESDW1	HUM_RSR_AE_ORIO HUM_RSR_PROJECT HUM_RSR_SCR	R	A code used in the human research system to identify the secondary processing staff owner for the submission related to a research study. If the person is a U of M staff member this will be their EMPLID.	05881664; 10857334; 21144886
SECONDARY_OWNER_FIRST_NAME	Owner First Name	Character	30	ERESDW1	HUM_RSR_AE_ORIO HUM_RSR_PROJECT HUM_RSR_SCR	R	The first name of a secondary processing staff owner for the submission related to a research study.	Adele; Mason; Supriya
SECONDARY_OWNER_LAST_NAME	Owner Last Name	Character	30	ERESDW1	HUM_RSR_AE_ORIO HUM_RSR_PROJECT HUM_RSR_SCR	R	The last name of a secondary processing staff owner for the submission related to a research study.	Banerjee; Samant; Sarter
SPECIMEN_IND	Specimen Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether specimens are a part of a specific research study.	Y = Yes; N = No; null
SPONSOR	Sponsor Identification Code	Character	6	ERESDW1	EXT_SPONSOR_TBL HUM_RSR_EXT_SPONSOR	R	A code identifying an external sponsor of research projects. This code is defined by DRDA (Division of Research Development Administration) for a sponsor.	003615; 392260; 744880

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
SPONSOR_CATEGORY	Sponsor Category	Character	100	ERESDW1	HUM_RSR_EXT_SPONSOR	R	A code identifying the funding type category of an external sponsor for a specific research study.	Government – State or Local; PI Discretionary Funds
SPONSOR_CLASS	Sponsor Class Code	Character	2	ERESDW1	EXT_SPONSOR_TBL	R	A code that classifies sponsors according to its business.	01 = US Government; 03 = US Foundation; 16 = Endowment
SPONSOR_LONGNAME	Sponsor Long Name	Character	256	ERESDW1	EXT_SPONSOR_TBL	R	The full name by which an external sponsor of research projects is known.	Arthritis Foundation; Baxter BioScience; MRL Pharmaceutical Services
SPONSOR_NAME	Sponsor Name	Character	256	ERESDW1	HUM_RSR_EXT_SPONSOR	R	The name by which the sponsor of a research study is known.	AstreZeneca, PLC National Cancer Institute; Johnson & Johnson
SPONSOR_PROJ_NBR	Sponsor Project Number	Character	256	ERESDW1	HUM_RSR_EXT_SPONSOR	R	The project number assigned by the sponsor.	1-U10-HL074422-01; Q184H050106
SPONSOR_SHORTNAME	Sponsor Short Name	Character	50	ERESDW1	EXT_SPONSOR_TBL	R	An abbreviated name by which an external sponsor of research projects is known.	CIRSE; DNAX; RPB
SPONSOR_TYPE	Sponsor Type Code	Character	1	ERESDW1	EXT_SPONSOR_TBL	R	A code used to indicate the type of sponsor.	F = Federal; I = Internal; N = Non-Federal
STDY_TM_EMPL_TRAIN_STDNT_IND	Study Team Employee, Trainee, Student Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether employees, trainees, or students of research study team members are part of a specific research study.	Y = Yes; N = No; null
STDY_TM_FAMILY_MEM_IND	Study Team Family Member Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether study team family members are part of a specific research study.	Y = Yes; N = No; null
STDY_TM_PATIENTS_IND	Study Team Patients Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether patients of research study team members are part of a specific research study.	Y = Yes; N = No; null
STEM_CELL_IND	Stem Cell Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether stem cells are part of a special research study.	Y = Yes; N = No; null

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
STUDY_TEAM_REPORT_DT	Study Team Report Date	Date		ERESDW1	HUM_RSR_AE_DETAIL	R	The date on which the adverse event was reported to the study team.	12/20/2006; 2/1/2007
SUBJ_RESP_FOR_COST_DETAIL	Subject Responsible for Cost Detail Text	Character	4000	ERESDW1	HUM_RSR_PROJECT_DETAIL	R	A textual description of the cost the subject will be responsible for during their participation in a research study.	Subjects will continue to be responsible for diagnostic tests and treatments they are receiving for xxx and other medical conditions that are not part of the study protocol and would ordinarily be incurred if the patients were not part of the study. Many standard laboratory tests are provided free of charge during the study so it is anticipated that the overall expenses for care of xxx during the study will be somewhat less than if the patient had not participated.
SUBJ_RESP_FOR_COST_OTHER_IND	Subject Responsible for Cost Uncovered Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT_DETAIL	R	A code indicating whether a research subject is responsible of other costs in relation to the research.	Y = Yes; N = No; null
SUBJ_RESP_FOR_COST_IND	Subject Responsible for Cost Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT_DETAIL	R	A code indicating whether a research subject is responsible for the cost subject's cost.	Y = Yes; N = No; null
SURVEY_IND	Survey Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether a survey is a part of a research study.	Y = Yes; N = No; null
TIME_IN_STATE_TEXT	Time In State Text	Character	256	ERESDW1	HUM_RSR_STATE_TRANSITION	R	A textual description of a time that a submission remained in a specific state. The specific state is indicated by the value in the Old State.	1004 hours 8 minutes 7 seconds; 100 hours 29 minutes 41 seconds; 381 hours 29 minutes 13 seconds

Physical Element Name	Logical Element Name	Format Type	Format Length	Data Set	Table Locations	Security Code	Element Definition	Examples of Valid Values
TO_DATE_INELIGIBLE_SCREEN	To Date Ineligible Screening Count	Number	8	ERESDW1	HUM_RSR_SCR	R	A number representing the count of ineligible screenings that have occurred to date for a research study.	6; 83; 16000
TO_DATE_SUBJ_DATA	To Date Subject Data Count	Number	8	ERESDW1	HUM_RSR_SCR	R	A number representing the count of subjects for which data was collected to date for a research study.	13; 47000; 111137
TO_DATE_WITHDRAW	To Date Withdrawal Count	Number	8	ERESDW1	HUM_RSR_SCR	R	A number representing the count of subject withdrawals to date for a research study.	5; 53; 666
UNDERGO_PROD_AT_UM_IND	Undergo Procedure At University of Michigan Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT_DETAIL	R	A code indicating whether the procedure will be conducted at the University of Michigan.	Y = Yes; N = No; null
VIABLE_NEONATE_IND	Viable Neonate Indicator Code	Character	1	ERESDW1	HUM_RSR_PROJECT	R	A code indicating whether viable neonates are part of a specific research study.	Y = Yes; N = No; null