

National Institutes of Health



NIH X12 194 Implementation Guide For the Competing Award Process

Version 2.0

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1. Purpose and Business Overview

1.1 Document Purpose

The purpose of the “NIH X12 194 Implementation Guide for the Competing Award Process” is to provide standardized data requirements and content to all users interested in submitting competitive grant application data to the National Institutes of Health (NIH) via the X12 194 (Grant or Assistance Application) transaction set. The guide provides a detailed explanation of the transaction set by defining uniform data content and identifying valid code tables. This will aid users in the successful encoding of grant application data from a proprietary format to the X12 194 standards required by NIH.

Expected users of this implementation guide include NIH grantee organizations and third party vendors that conduct business with NIH on behalf of a grantee organization (i.e., grantee organization agents).

1.2 Version and Release

The “NIH X12 194 Implementation Guide for the Competing Award Process” is based on the Accredited Standards Committee (ASC) X12 standards, approved for publication in December of 1997, referred to as Version 4 Release 1 (004010).

1.3 Business Usage and Definition

NIH has deployed a pilot EDI system to receive and validate competitive grant application data. Grantee organizations (or their agents) use a subset of the 194 to encode the data for transmission to this pilot system.

The NIH EDI pilot system is being deployed as a phased implementation. Phase one, which is currently underway, accepts test data for the following sections of the grant application: face page, abstract, description of performance sites and key personnel, research plan specific aims, and the budget. Phase two, for which this manual is written, is an extension of phase one, supporting the entire competitive application.

Phase two has several constraints. First, as with phase one, only test data is accepted. Second, only competing continuations and revisions are supported (i.e., no supplements or new applications). Last, only single project research applications are supported. This means that applications for Research Career Awards, Research Training Grants, or Construction Grants, as well as applications with subprojects, consortium arrangements, or foreign components will not be accepted during phase two.

1.4 References

1. “ASC X12 194 Transaction Set. Federal Implementation Conventions.” Version 004010. September 30, 1998.
2. U.S. Department of Health and Human Services, Public Health Service, Grant Application (PHS 398).” OMB No. 0925-0001. Form approved through 02/28/2001.

1.5 Terms and Abbreviations

194	X12 Grant or Assistance Application
398	NIH Grant Application
AO	Administrative Officer
ASC	Accredited Standards Committee
DUNS	Data Universal Numbering System
EDI	Electronic Data Interchange
EIN	Entity Identification Number
GUIDe	Government User Identifier
IACUC	Institutional Animal Care and Use Committee
IC	Implementation Convention
IPF	Institutional Profile
IRB	Institutional Review Board
NIH	National Institutes of Health
OPF	Organizational Profile
OS	Other Support
PHS	Public Health Service
PI	Principal Investigator
PPF	Professional Profile
RFA	Request For Application
SO	Signing Official
SSN	Social Security Number

1.6 Organization of Document

This document, the “NIH X12 194 Implementation Guide for the Competing Award Process”, contains three major sections. Section 1 introduces the manual. Section 2 provides a data overview, and section 3 presents the implementation guidelines for the 194 transaction set. This document also contains one appendix, which provides a sample PHS 398 application and associated X12 194 transaction set.

1.7 How to Use This Document

This manual is written for the technical user who understands EDI terms and concepts. It cannot be used as a standalone document; it must be used in conjunction with the 194 Federal Implementation Conventions (ICs) [1], and the PHS 398 Application Kit [2].

This document presents, in tabular form, the 194 data segments used in phase two of the NIH EDI pilot. Each table contains the complete set of data elements comprising the segment, as well as all data codes and qualifiers processed by NIH. Each table also contains any implementation notes specific to NIH requirements.

This guide specifies the usage for each data segment and data element applicable to phase two of the EDI pilot. The definitions for the usage codes are provided below.

Usage	Expansion	Meaning
R	Required	This item must be used to be compliant with this guide.
O	Optional	The presence of this item is at the option of the sender.
C	Conditional	If the first element specified in the condition is present, then all other elements must be present.
N/U	Not Used	This item should not be used when complying with this guide.

1.8 Respondent Burden

This information collection activity is linked to the *U.S. Department of Health and Human Services, Public Health Service, Grant Application (PHS 398, Rev. 5/95)*. The PHS 398 form is approved through 02/28/2001, OMB No. 0925-0001.

The Public Health Service (PHS) estimates that it will take approximately 35 hours to complete this application for a regular research project grant. This estimate does not include time for development of the scientific plan. Items such as human subjects and vertebrate animals are cleared and accounted for separately, and are therefore also not part of the time estimate. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a current valid OMB control number. If you have any comments regarding this burden estimate or any other aspect of this collect of information, including suggestions for reducing this burden, send comments to: NIH, Project Clearance office, 6701 Rockledge Drive, MSC 7730, Bethesda, MD 20892-7730, ATTN: PRA (0925-0001). **Do not send applications to this address.**

2. Data Overview

2.1 Information Flows

The transmission of competitive grant application data to NIH takes place as shown:

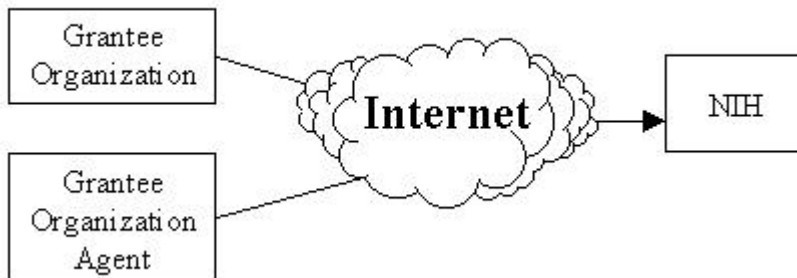


Figure 2.1. Competitive Grant Application Information Flow

2.2 Data Usage by Business Usage

The X12 194 is divided into two tables: Header and Detail.

- Table 1, the Header level, provides administrative data pertaining to the application, including the application type, how the research plan is submitted, information about the administrative and signing officials, and information about the applicant organization.
- Table 2, the Detail level, provides information pertaining to project dates and resources, personnel and other support, the budget, performance sites, assurances and certifications, and information about human subjects and vertebrate animals.

2.2.1 HL Loops

When specifying application data in Table 2, HL loops are used to define specific threads of information. Each HL loop is identified by an HL level code. This guide recognizes three HL level codes: Project (PC), Key Person (26), and Other Support (OS).

1. Project: This HL loop is used to provide project-related information, including dates, resources, budget data, performance sites, and information on human subjects and vertebrate animals.
2. Key Person: This HL loop is used to identify information about a key person, including active or pending Other Support.

3. Other Support: This HL loop is used to identify the Other Support associated with a key person, including other support dates, sources, percent effort, and description of the overlap. One iteration of this loop is required per Other Support project (active or pending).

X12 HL loop types are hierarchical in structure. The following diagram depicts the relationships between the three HL loop types supported in phase two of the NIH pilot.

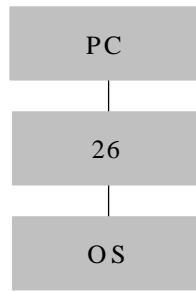


Figure 2-2. HL Loop Type Hierarchy

With each HL loop type, only certain segments can be specified. The following table lists the segments that comprise table 2 of the 194 transaction set, and for each segment (or set of related segments), which HL loop types support the segment (as defined by phase two of the NIH pilot).

194 Segment	PC	26	OS
QTY		✓	
DTM	✓		
PAM	✓		✓
NX1	✓		
YNQ	✓		
N9/L11/MTX	✓		
INX/K3	✓		
PPL/PD/PDD	✓		
LX/NM1-N4	✓	✓	✓
PER		✓	
DMG		✓	
EMS		✓	
N9/MTX	✓	✓	✓
DEG/FOS/N1		✓	

Table 2-1. HL Loop Segment Usage

2.2.2 Budget Category Code Hierarchy

The 194 permits a hierarchical specification of budget data. For example, salaries and fringe benefits are aggregated to calculate labor costs. Labor costs are aggregated with equipment costs, inpatient costs, outpatients costs (and others) to calculate total direct costs. Each cost is associated with a code.

The hierarchy of budget category codes supported by phase two of the NIH pilot is shown below.

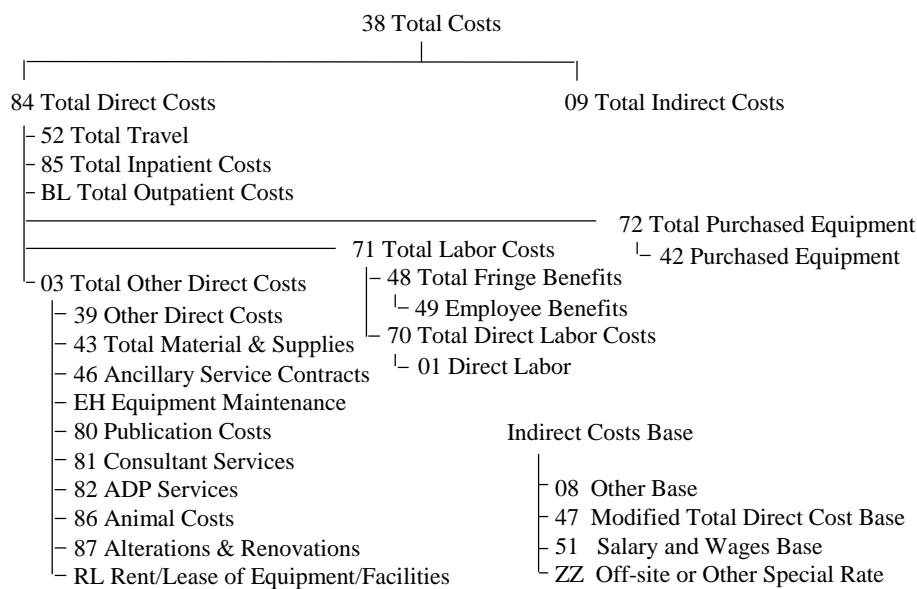


Figure 2-3. Budget Category Code Hierarchy

2.3 Data/Transaction Set Model with Usage Matrix

The following matrix identifies the PHS 398 items supported in the NIH EDI pilot. The matrix correlates 398 items with 194 data elements and 194 codes. The 194 codes are specified in parentheses.

Page	398 Item	Item Definition	194 Reference
AA.1	Title of Project	Application Title	1/N901/060 (4W) 1/MTX02/080
AA.2	RFA Number	Request For Application Number	1/BGN06/020
AA.2	RFA Title	Request For Application Title	1/N901/060 (KS) 1/MTX02/080
AA.3	New Investigator	New investigator	1/N901/060 (L4) 1/N902/060 (J.1)
AA.3a	Principal Investigator (PI)	PI last name PI first name PI middle name PI name prefix PI name suffix PI government user ID	2/HL03/010 (26) 2/NM101/340 (9P) 2/NM103/340 2/NM104/340 2/NM105/340 2/NM106/340 2/NM107/340 2/N901/400 (JD) 2/N902/400
AA.3b	PI Degrees	PI degree PI degree date PI major PI area of specialization Institution name	2/DEG04/420 2/DEG02/420 (CM) 2/DEG03/420 2/FOS01/430 (M) 2/FOS04/430 2/FOS05/430 2/N101/440 (1R) 2/N102/440
AA.3c	PI Social Security No	PI SSN	<i>See Page KK</i>
AA.3d	PI Position Title	PI position title	2/N901/400 (P5) 2/N903/400
AA.3e	PI Mailing Address	PI street address PI city PI state PI zip code PI country code PI county PI email address PI mail stop	2/N301/360 2/N302/360 2/N401/370 2/N402/370 2/N403/370 2/N404/370 2/N405/370 (CY) 2/N406/370 2/PER07/375 (EM) 2/PER08/375 2/PER09/375
AA.3f	PI Department	PI department	2/N901/400 (19) 2/N907-1/400 (DP) 2/N907-2/400

Page	398 Item	Item Definition	194 Reference
AA.3g	PI Major Subdivision	PI major subdivision	2/N901/400 (19) 2/N903/400
AA.3h	PI Telephone and Fax	PI telephone number PI facsimile number	2/PER03/375 (TE) 2/PER04/375 2/PER05/375 (FX) 2/PER06/375
AA.4	Human Subjects	Exemption number Assurance of compliance number IRB review pending IRB review type (full or expedited) IRB approval date	2/N901/100 (WI) 2/N902/100 2/N901/100 (F4) 2/N902/100 2/N903/100 (“Pending”) 2/N903/100 (“Full” or “Expedited”) 2/N904/100
AA.5	Vertebrate Animals	Animal welfare assurance number IACUC review pending IACUC approval date	2/N901/100 (Y9) 2/N902/100 2/N903/100 (“Pending”) 2/N904/100
AA.6	Proposed Period of Support – From	Estimated start date	2/DTM01/050 (193) 2/DTM02/050
AA.6	Proposed Period of Support – Through	Estimated end date	2/DTM01/050 (194) 2/DTM02/050
AA.6	Proposed Period of Support	Duration of project (in months)	2/PAM01/060 (A3) 2/PAM02/060 2/PAM03-1/060 (MO)
AA.7	Costs Requested for Initial Budget Period	Direct costs Total Costs	2/PPL04/170 (1) 2/PD07/190 (84) 2/PDD03/200 2/PPL04/170 (1) 2/PD07/190 (38) 2/PDD03/200
AA.8	Costs Requested for Proposed Period of Support	Direct costs Total costs	2/PPL04/170 (T) 2/PD07/190 (84) 2/PDD03/200 2/PPL04/170 (T) 2/PD07/190 (38) 2/PDD03/200

Page	398 Item	Item Definition	194 Reference
AA.9	Applicant Organization	Organization name Organization street address Organization city Organization state Organization zip code Organization country code Organization county Organization IPF code	1/NM101/090 (SE) 1/NM103/090 1/N201/100 1/N301/110 1/N302/110 1/N401/120 1/N402/120 1/N403/120 1/N404/120 1/N405/120 (CY) 1/N406/120 1/N901/130 (CR) 1/N902/130
AA.10	Type of Organization	Type of Organization Public – Federal Public – State Public – Local Private Nonprofit For Profit – General For Profit – Small Business	2/NX101/080 (2R) (2F) (C6) (A8) (B9) (21)
AA.11	Organizational Component Code	Organizational component code	N/A
AA.12	Entity Identification Number	EIN DUNS Organization congressional district	2/N901/130 (EI) 2/N902/130 1/NM108/090 (1,9) 1/NM109/090 2/N901/130 (5C) 2/N902/130

Page	398 Item	Item Definition	194 Reference
AA.13	Administrative Official (AO)	AO last name	1/NM101/090 (AD)
		AO first name	1/NM103/090
		AO middle name	1/NM104/090
		AO name prefix	1/NM105/090
		AO name suffix	1/NM106/090
		AO government user ID	1/NM107/090
			1/N901/130 (JD)
		AO street address	1/N902/130
			1/N301/110
			1/N302/110
		AO city	1/N401/120
		AO state	1/N402/120
		AO zip code	1/N403/120
		AO country code	1/N404/120
		AO county	1/N405/120 (CY)
			1/N406/120
		AO title	1/N901/130 (P5)
			1/N903/130
		AO telephone number	1/PER03/140 (TE)
			1/PER04/140
		AO facsimile number	1/PER05/140 (FX)
			1/PER06/140
		AO email address	1/PER07/140 (EM)
			1/PER08/140
		AO mail stop	1/PER09/140

Page	398 Item	Item Definition	194 Reference
AA.14	Signing Official (SO)	SO last name SO first name SO middle name SO name prefix SO name suffix SO government user ID SO street address SO city SO state SO zip code SO country code SO county SO title SO telephone number SO facsimile number SO email address SO mail stop	1/NM101/090 (1B) 1/NM103/090 1/NM104/090 1/NM105/090 1/NM106/090 1/NM107/090 1/N901/130 (JD) 1/N902/130 1/N301/110 1/N302/110 1/N401/120 1/N402/120 1/N403/120 1/N404/120 1/N405/120 (CY) 1/N406/120 1/N901/130 (P5) 1/N903/130 1/PER03/140 (TE) 1/PER04/140 1/PER05/140 (FX) 1/PER06/140 1/PER07/140 (EM) 1/PER08/140 1/PER09/140
AA.15	PI Assurance	PI signature and date	N/A
AA.16	Applicant Organization Certification and Acceptance	Application date	1/BGN03/020
BB	Abstract	Abstract text	2/N901/100 (L4) 2/N902/100 (A) 2/MTX02/110 2/MTX03/110

Page	398 Item	Item Definition	194 Reference
BB	Performance Sites	Principal performance site Organization name Organization city Organization state - or - Other performance sites. Organization name Organization city Organization state	1/NM101/090 (FA) 1/NM103/090 1/N201/100 1/N401/120 1/N402/120 - or - 2/NM101/340 (61) 2/NM103/340 2/NM201/350 2/NM401/370 2/NM402/370
BB	Key Personnel	Key Personnel Name information Last name First name Middle Name Name prefix Name suffix Government User ID Organization name Organization DUNS Role on project	2/HL03/010 (26) 2/NM101/340 (9K) 2/NM103/340 2/NM104/340 2/NM105/340 2/NM106/340 2/NM107/340 2/N901/400 (JD) 2/N902/400 2/N201/350 2/NM108/340 (1, 9) 2/NM109/340 2/PD07/190 (01) 2/PD09/190
DD	Initial Budget Period	Detailed budget for initial budget period	2/PPL04/170 (1)
DD	From	Budget period start date	2/PD02/190
DD	Through	Budget period length	2/PDD01/200
DD	Name	Government User ID of person or person's name	2/PD07/190 (01, 49) 2/PD08/190
DD	Role on Project	Role on project	2/PD07/190 (01, 49) 2/PD09/190
DD	Type Appt	Number of appointment months	2/PD07/190 (01, 49) 2/PDD02/200
DD	% Effort on Project	Level of effort as a percent	2/PD07/190 (01, 49) 2/PDD04/200
DD	Inst. Base Salary	Institutional base salary	2/PD07/190 (01, 49) 2/PD04/190
DD	Salary Requested	Dollar amount for requested salary	2/PD07/190 (01) 2/PDD03/200
DD	Fringe Benefits	Dollar amount for fringe benefits	2/PD07/190 (49) 2/PDD03/200

Page	398 Item	Item Definition	194 Reference
DD	Totals	N/A (NIH will calculate)	N/A
DD	Subtotals (NIH will calculate subtotals if not specified in application)	Total salaries requested Total fringe benefits	2/PD07/190 (70) 2/PDD03/200 2/PD07/190 (48) 2/PDD03/200
DD	[any budget item description]	Further description for any budgeted item	2/PD07/190 (except 01,49) 2/PD09/190
DD	Consultant Costs	Consultant costs	2/PD07/190 (81) 2/PDD03/200
DD	Equipment	Equipment costs – itemized	2/PD07/190 (42) 2/PDD03/200
DD	Supplies	Cost of supplies	2/PD07/190 (43) 2/PDD03/200
DD	Travel	Domestic and foreign travel costs	2/PD07/190 (52) 2/PDD03/200
DD	Inpatient	Inpatient patient care costs	2/PD07/190 (85) 2/PDD03/200
DD	Outpatient	Outpatient patient care costs	2/PD07/190 (BL) 2/PDD03/200
DD	Alterations and Renovations	Cost of alterations and renovations	2/PD07/190 (87) 2/PDD03/200
DD	Other Expenses	Costs for any other expenses	2/PD07/190 (39) 2/PDD03/200
DD	N/A	Other itemized direct costs Ancillary service contracts Equipment maintenance Publication Costs ADP services Animal Costs Rent/Lease of equipment/facilities	2/PDD03/200 2/PD07/190 (46) 2/PD07/190 (EH) 2/PD07/190 (80) 2/PD07/190 (82) 2/PD07/190 (86) 2/PD07/190 (RL)
DD	Subtotal Direct Costs	N/A (NIH will calculate)	N/A
DD	Consortium/Contractual Costs	Consortium/Contractual costs are not supported in this release	N/A
DD	Total Direct Costs	Same as AA.7	2/PPL04/170 (1) 2/PD07/190 (84) 2/PDD03/200

Page	398 Item	Item Definition	194 Reference
EE	Additional Years of Support Requested	For each year (2,3,4,5) of additional support	2/PPL04/170 (2,3,4,5)
EE	Personnel	Salary and fringe benefits	2/PD07/190 (71) 2/PDD03/200
EE	Consultant Costs	Consultant costs	2/PD07/190 (81) 2/PDD03/200
EE	Equipment	Equipment costs – total	2/PD07/190 (72) 2/PDD03/200
EE	Supplies	Cost of supplies	2/PD07/190 (43) 2/PDD03/200
EE	Travel	Cost of travel	2/PD07/190 (52) 2/PDD03/200
EE	Inpatient	Inpatient patient care costs	2/PD07/190 (85) 2/PDD03/200
EE	Outpatient	Outpatient patient care costs	2/PD07/190 (BL) 2/PDD03/200
EE	Alterations and Renovations	Cost of alterations and renovations	2/PD07/190 (87) 2/PDD03/200
EE	Other Expenses	Costs for any other expenses	2/PD07/190 (39) 2/PDD03/200
EE	N/A	Other costs itemized for the 194 Ancillary service contracts Equipment maintenance Publication Costs ADP services Animal Costs Rent/Lease of equipment/facilities	2/PDD03/200 2/PD07/190 (46) 2/PD07/190 (EH) 2/PD07/190 (80) 2/PD07/190 (82) 2/PD07/190 (86) 2/PD07/190 (RL)
EE	Total Direct Costs	Same as AA.8	2/PPL04/170 (T) 2/PD07/190 (84) 2/PDD03/200
EE	Justification	Budget justification	2/N901/100 (L4) 2/N902/100 (C.1) 2/MTX02/110 2/MTX03/110

Page	398 Item	Item Definition	194 Reference
FF	Name	Biographical Sketch PI or key person Last name First name Middle Name Name prefix Name suffix Government User ID	2/HL03/010 (26) 2/NM101/340 (9P,9K) 2/NM103/340 2/NM104/340 2/NM105/340 2/NM106/340 2/NM107/340 2/N901/400 (JD) 2/N902/400
FF	Position Title	Position title	2/N901/400 (P5) 2/N903/400
FF	Education/Training	Institution and Location Institution name Degree Year Field of study Area of specialization	2/N101/440 (1R) 2/N102/440 2/DEG04/420 2/DEG02/420 (CM) 2/DEG03/420 2/FOS01/430 (M) 2/FOS04/430 2/FOS05/430
FF	Research and Professional Experience	Research and professional experience Previous employment Experience Honors Memberships Publications	2/N901/400 (L4) 2/N902/400 (D.2) 2/N902/400 (D.1) 2/N902/400 (D.3) 2/N902/400 (D.4) 2/N902/400 (D.5,D.5.1) 2/MTX02/410 2/MTX03/410
GG	Other Support (OS)	Other support	2/HL03/010 (OS)
GG	Status	Active Other Support Pending Other Support	2/PAM01/060 (37) 2/PAM01/060 (A3)
GG	Project Dates	OS project start date OS project end date	2/PAM07/060 (193) 2/PAM08/060 2/PAM10/060 (194) 2/PAM11/060
GG	Annual Direct Costs	Annual direct costs	2/PAM04/060 (F) 2/PAM05/060
GG	Percent Effort	Percent effort	2/PAM13/060 (14) 2/PAM14/060

Page	398 Item	Item Definition	194 Reference
GG	Active Support Project Information	Project number Project title	2/N901/400 (CT) 2/N902/400 2/MTX02/410
GG	Pending Support Project Information	Project number Project title	2/N901/400 (BD) 2/N902/400 2/MTX02/410
GG	Source	Source	2/NM101/340 (92) 2/NM103/340
GG	Major Goals	Major goals	2/N901/400 (K5) 2/MTX02/410
GG	Overlap	Overlap	2/N901/400 (YV) 2/MTX02/410
GG	Principal Investigator	OS PI PI last name PI first name PI middle name PI name prefix PI name suffix	2/NM101/340 (9P) 2/NM103/340 2/NM104/340 2/NM105/340 2/NM106/340 2/NM107/340
HH	Facilities	Describe laboratory, clinical, animal, computer, office, and other facilities	2/N901/100 (L4) 2/N902/100 (C.2) 2/MTX02/110 2/MTX03/110
HH	Major Equipment	Major equipment	2/N901/100 (L4) 2/N902/100 (C.3) 2/MTX02/110 2/MTX03/110
II	Type of Application	Revision Revision of application number Cite application number in N902	1/BGN07/020 (6R) 1/N901/060 (6M) 1/N902/060
II	Type of Application	Competing continuation Continuation of grant number Cite grant number in N902	1/BGN07/020 (6C) 1/N901/060 (CT) 1/N902/060
II	Inventions and Patents	Yes/No Previously reported?	2/N901/100 (L4) 2/N902/100 (I.6) 2/MTX02/110 (Reported, Not Reported)

Page	398 Item	Item Definition	194 Reference
II	Change of PI	Name of former PI Last name First name Middle name Name prefix Name suffix Government User ID	1/NM101/090 (AZ) 1/NM103/090 1/NM104/090 1/NM105/090 1/NM106/090 1/NM107/090 1/N901/130 (JD) 1/N902/130
II	Foreign Application	Applications with foreign components are not supported in this release	N/A
II	Assurances/Certifications	Human Subjects Vertebrate Animals Debarment and Suspension Drug-Free Workplace Lobbying Delinquent Federal Debt Research Misconduct Discrimination Regulations Financial Conflict of Interest Response to condition Explanatory text for assurance/certification	see IRB information see IACUC info 2/YNQ01/090 (I8) 2/YNQ01/090 (H5) 2/YNQ01/090 (H0, H4) 2/YNQ01/090 (I7) 2/YNQ01/090 (H6) 2/YNQ01/090 (H8) 2/YNQ01/090 (H9) 2/YNQ02/090 2/YNQ05,6,7/090
II	Program Income	Budget period, anticipated amount, source(s) (all provided in one text field)	2/N901/100 (L4) 2/N902/100 (E.4) 2/MTX02/110 2/MTX03/110
II	Indirect Costs	DHHS regional office or other agency DHHS agreement dated	2/NM101/340 (K8) 2/NM103/340 2/N901/400 (AH) 2/N903/400 “Current” or “Pending” 2/N904/400
II	Calculation	Initial budget period Entire proposed project period Indirect costs code Amount of base Rate applied Indirect costs	2/PPL04/170 (1) 2/PPL04/170 (T) 2/PD07/190 (08, 47, 51, ZZ, or 09) 2/PD03-01/190 (P1) 2/PDD02/200 2/PD04/190 2/PDD03/200

Page	398 Item	Item Definition	194 Reference
II	Check Appropriate Boxes	Check appropriate boxes Salary and wages base Modified total direct cost base Off-site, other special rate, or more than one rate involved Other base	2/PD07/190 51 47 ZZ 08
II	Explanation	Explanation	2/N901/100 (L4) 2/N902/100 (E.7) 2/MTX02/110 2/MTX03/100
II	Smoke-Free Workplace	Smoke-free workplace Response to condition Explanatory text	2/YNQ01/090 (H7) 2/YNQ02/090 2/YNQ05,6,7/090
JJ	Personnel Report – Name	Identify as PI Identify as key person Last name First name Middle name Prefix Suffix Government user ID	2/NM101/340 (9P) 2/NM101/340 (9K) 2/NM103/340 2/NM104/340 2/NM105/340 2/NM106/340 2/NM107/340 2/N901/400 (JD) 2/N902/400
JJ	Degrees	<i>NIH has the degree information from the previous application.</i>	N/A
JJ	SSN	Social Security Number	2/N901/400 (SY) 2/N902/400
JJ	Role on Project	<i>NIH has the project role from the previous application.</i>	N/A
JJ	Date of Birth	Date of birth	2/DMG02/380
JJ	Annual % Effort	Annual percent effort	2/QTY01/020 (37) 2/QTY02/020
KK	PI Social Security No	PI SSN	2/N901/400 (SY) 2/N902/400
KK	Personal Data on PI	PI personal data	2/HL03/010 (26)
KK	Date of Birth	PI date of birth	2/DMG02/380
KK	Gender	PI gender	2/DMG03/380
KK	Race and/or Ethnic Origin	PI race and/or ethnic origin	2/DMG05/380

Page	398 Item	Item Definition	194 Reference
N/A	N/A	Identification of Federal agency Cite DUNS Number Use value of 927645168	1/NM101/090 (BY) 1/NM108/090 (1) 1/NM109/090
N/A	N/A	How research plan is submitted: As paper mailed to NIH As NIH file upload As X12 841 transaction set	1/PWK01/050 (SD) 1/PWK02/050 (BM) 1/PWK02/050 (DA) 1/PWK02/050 (EL) 1/N901/060 (TN) 1/N902/060 1/N907/060 C04001 (7U) 1/N907/060 C04002
N/A	N/A	Gender and minority study matrix Study title Gender and number of members for each racial/ethnic group	2/N901/100 (43) 2/N903/100 2/MTX02/110 2/INX/120 2/K301/130
N/A	N/A	Research plan specific aims	2/N901/100 (L4) 2/N902/100 (B.2) 2/MTX02/110 2/MTX03/110
N/A	N/A	Cover letter	2/N901/100 (L4) 2/N902/100 (F.2) 2/MTX02/110 2/MTX03/110

2.4 Applications and Profiles

Grantee organizations and users must register with NIH before being referenced on an application. Once registered, the grantee organization maintains its Organizational Profile (OPF) and each user maintains a Professional Profile (PPF). When submitting grant application data to NIH via EDI, there are business rules that govern how information in the application affects the profiles. In general, grant application data elements:

- must match the registered profile values, or
- are stored as part of the application, but do not change the profile, or
- change the profile.

The specific business rules are described below. Note that not all the data elements listed are required to be present on an application.

2.4.1 Organizational Profile

With respect to the applicant organization, no organizational data submitted via EDI affects the OPF. The following grant application data elements *must* match OPF values registered with NIH. If not, the transaction is rejected.

- Institutional Profile (IPF) code
- DUNS number
- EIN

The following grant application data elements *should* match OPF values registered with NIH. If not, the transaction is accepted, but the dissimilar data elements are ignored, and an email message is returned to the grantee identifying the inconsistency(ies).

- organization name
- organization type
- congressional district
- department (for the PI)
- school or major subdivision (for the PI)

The following data elements are stored as part of the application, but do not change the OPF.

- address (street address, city, state, etc.)
- assurance and certification data

2.4.2 Professional Profile

NIH uses a Unique Person Algorithm (based on various PPF data elements) to uniquely identify key individuals on a grant application. If the algorithm *fails* (i.e., cannot uniquely identify an individual), the transaction is rejected. Note that failure to recognize even one key person causes the grant application to be rejected. If the algorithm succeeds (i.e., uniquely identifies an individual), PPF data elements are handled as follows.

The following grant application data elements *must* match PPF values registered with NIH. If not, the transaction is rejected.

- Government User Identifier (GUIDe)
- Social Security Number (SSN) – note that an invalid GUIDe or SSN will result in the algorithm failing. They are listed here only for completeness.

The following grant application data elements *should* match PPF values registered with NIH. If not, they are stored as part of the application (they do not change the PPF), but an email message is returned to the grantee identifying the inconsistency(ies).

- name
- date of birth
- gender
- race/ethnicity

The following data elements are stored as part of the application, but do not change the user's PPF.

- position title
- address (street address, city, state, etc.)
- contact data (phone, fax, email)
- degree (i.e., education)
- research and professional experience

Publications are handled as follows. Each publication specified in the grant application is compared to the PPF registered with NIH. If a match is found, the publication is stored as part of the application. If a match is not found,

- the publication is stored as part of the application
- the publication is added to the individual's PPF
- an email message is returned to the grantee identifying the PPF update.

2.5 General Processing Rules

NIH applies some general rules when processing data streams. The NIH processing rules for EDI transactions containing competing applications are as follows.

1. There are 194 data segments, data elements, and codes not supported by NIH. Any unsupported information included in the data stream is ignored.
2. This implementation guide restricts the length of certain data elements. If a data element exceeds an NIH length constraint, the data stream is rejected.
3. Some 194 data elements comprise multiple values (e.g., a person can have multiple position titles). For some of these data elements, NIH only permits a single value (e.g., NIH only allows a single title to be specified for a person). When this scenario arises, only one value is stored with the application. The grantee is notified via email of which value was accepted.

NIH requires the following HL loops to be present in the 194 transaction set: the Project Loop ("PC") and one iteration of the Key Person Loop ("26") for the PI. Within these two loops, NIH requires the following data elements. If any of these data elements are missing, the transaction is rejected.

Page	398 Item	Item Definition	194 Reference
AA.1	Title of Project	Application Title	1/N901/060 (4W) 1/MTX02/080
AA.3a	Principal Investigator (PI)	PI last name PI first name	2/HL03/010 (26) 2/NM101/340 (9P) 2/NM103/340 2/NM104/340
AA.3b	PI Degrees	PI degree	2/DEG04/420
AA.3d	PI Position Title	PI position title	2/N901/400 (P5) 2/N903/400
AA.3e	PI Mailing Address	PI street address PI city PI state PI zip code PI email address	2/N301/360 2/N302/360 2/N401/370 2/N402/370 2/N403/370 2/PER07/375 (EM) 2/PER08/375
AA.3f	PI Department	PI department	2/N901/400 (19) 2/N907-1/400 (DP) 2/N907-2/400
AA.3g	PI Major Subdivision	PI major subdivision	2/N901/400 (19) 2/N903/400
AA.3h	PI Telephone and Fax	PI telephone number PI facsimile number	2/PER03/375 (TE) 2/PER04/375 2/PER05/375 (FX) 2/PER06/375
AA.4	Human Subjects	<i>If assurance number is present, review pending or approval date must be present</i> Assurance of compliance number IRB review pending or review type IRB approval date	2/N901/100 (F4) 2/N902/100 2/N903/100 2/N904/100
AA.5	Vertebrate Animals	<i>If assurance number is present, review pending or approval date must be present</i> Animal welfare assurance number IACUC review pending IACUC approval date	2/N901/100 (Y9) 2/N902/100 2/N903/100 2/N904/100
AA.6	Proposed Period of Support – From	Estimated start date	2/DTM01/050 (193) 2/DTM02/050
AA.6	Proposed Period of Support – Through	Estimated end date Duration of project (in months)	2/DTM01/050 (194) 2/DTM02/050 - or - 2/PAM01/060 (A3) 2/PAM02/060 2/PAM03-1/060 (MO)
AA.7	Costs Requested for Initial Budget Period	Direct costs Total Costs	2/PPL04/170 (1) 2/PD07/190 (84) 2/PDD03/200 2/PPL04/170 (1) 2/PD07/190 (38) 2/PDD03/200

Page	398 Item	Item Definition	194 Reference
AA.8	Costs Requested for Proposed Period of Support	Direct costs Total costs	2/PPL04/170 (T) 2/PD07/190 (84) 2/PDD03/200 2/PPL04/170 (T) 2/PD07/190 (38) 2/PDD03/200
AA.9	Applicant Organization	Organization name Organization street address Organization city Organization state Organization zip code	1/NM101/090 (SE) 1/NM103/090 1/N201/100 1/N301/110 1/N401/120 1/N402/120 1/N403/120
AA.10	Type of Organization	Type of Organization	2/NX101/080
AA.13	Administrative Official (AO)	AO last name AO first name AO street address AO city AO state AO zip code AO title AO telephone number AO facsimile number AO email address	1/NM101/090 (AD) 1/NM103/090 1/NM104/090 1/N301/110 1/N401/120 1/N402/120 1/N403/120 1/N901/130 (P5) 1/N903/130 1/PER03/140 (TE) 1/PER04/140 1/PER05/140 (FX) 1/PER06/140 1/PER07/140 (EM) 1/PER08/140
AA.14	Signing Official (SO)	SO last name SO first name SO street address SO city SO state SO zip code SO title SO telephone number SO facsimile number SO email address	1/NM101/090 (1B) 1/NM103/090 1/NM104/090 1/N301/110 1/N401/120 1/N402/120 1/N403/120 1/N901/130 (P5) 1/N903/130 1/PER03/140 (TE) 1/PER04/140 1/PER05/140 (FX) 1/PER06/140 1/PER07/140 (EM) 1/PER08/140
AA.16	Certification and Acceptance	Application date	1/BGN03/020

Page	398 Item	Item Definition	194 Reference
II	Type of Application	<p><i>Application must be identified as either a revision or a competing continuation.</i></p> <p>Revision First transmission Revision of application number Cite application number in N902</p> <p>Competing continuation First transmission Continuation of grant number Cite grant number in N902</p>	<p>1/BGN07/020 (6R) 1/BGN01/020 (00) 1/N901/060 (6M) 1/N902/060</p> <p>1/BGN07/020 (6C) 1/BGN01/020 (00) 1/N901/060 (CT) 1/N902/060</p>
II	Indirect Costs	<p><i>If Rate Applied is present, all other fields must be present.</i></p> <p>Initial budget period Entire proposed project period Indirect costs base</p> <p>Amount of base</p> <p>Rate applied Indirect costs</p>	<p>2/PPL04/170 (1) 2/PPL04/170 (T) 2/PD07/190 (08, 47, 51, or ZZ) 2/PD03-01/190 (P1) 2/PDD02/200 2/PD04/190 2/PDD03/200</p>
II	DHHS Agreement	<p><i>If Rate Applied is present, one of the following two fields must be present.</i></p> <p>DHHS regional office or other agency</p> <p>DHHS agreement dated</p>	<p>2/NM101/340 (K8) 2/NM103/340 2/N901/400 (AH) 2/N903/400 2/N904/400</p>
II	Explanation	<p><i>If Indirect Cost Base (2/PD07/190) is either 08 or ZZ, an explanation is required.</i></p> <p>Explanation</p>	<p>2/N901/100 (L4) 2/N902/100 (E.7) 2/MTX02/110 2/MTX03/100</p>

2.6 ASCII Text

When submitting grant application data to NIH via EDI, grantee organizations encode the data using the 7-bit American Standard Code for Information Interchange (ASCII) bit pattern. This encoding scheme does not permit the representation of many foreign language characters (e.g., the Ä). This limitation is most apparent when specifying abstracts, project titles and publication titles containing special characters (e.g., mathematical characters). For the EDI pilot, NIH recommends providing a brief description of the special character. For example, use *delta* in lieu of δ , or use *small a, umlaut* in lieu of ä.

3. 194 Transaction Set

The X12 194 transaction set is used by grantee organizations (or their agents) to submit competitive grant application data to NIH. A single transmission of this transaction set shall be used to submit a single application. For phase two of the NIH EDI pilot, the submitted application shall contain test data.

Heading:

	<u>Pos</u> <u>No</u>	<u>Seg</u> <u>ID</u>	<u>Name</u>	<u>Req</u> <u>Des</u>	<u>Max</u> <u>Use</u>	<u>Repeat</u>
R	010	ST	Transaction Set Header	M	1	
R	020	BGN	Beginning Segment	M	1	
N/U	030	DTM	Date/Time Reference	O	>1	
N/U	040	LDT	Lead Time	O	>1	
O	050	PWK	Paperwork	O	>1	
LOOP ID - N9						>1
O	060	N9	Reference Number	O	1	
N/U	070	L11	Business Instructions	O	>1	
O	080	MTX	Text	O	>1	
LOOP ID - NM1						>1
R	090	NM1	Individual or Organizational Name	O	1	
O	100	N2	Additional Name Information	O	1	
O	110	N3	Address Information	O	2	
O	120	N4	Geographic Location	O	1	
O	130	N9	Reference Number	O	>1	
O	140	PER	Administrative Communications Contact	O	>1	

Detail:

	<u>Pos</u> <u>No</u>	<u>Seg</u> <u>ID</u>	<u>Name</u>	<u>Req</u> <u>Des</u>	<u>Max</u> <u>Use</u>	<u>Repeat</u>
			LOOP ID - HL			>1
R	010	HL	Hierarchical Level	M	1	
O	020	QTY	Quantity	O	>1	
N/U	030	AMT	Monetary Amount	O	>1	
O	050	DTM	Date/Time Reference	O	>1	
O	060	PAM	Period Amount	O	>1	
N/U	070	HSD	Health Care Services Delivery	O	>1	
O	080	NX1	Property or Entity Identification	O	1	
O	090	YNQ	Yes/No Question	O	>1	
			LOOP ID - N9			>1
O	100	N9	Reference Number	O	1	
N/U	105	L11	Business Instructions	O	>1	
O	110	MTX	Text	O	>1	
			LOOP ID - INX			>1
O	120	INX	Index Detail	O	1	
O	130	K3	File Information	M	>1	
			LOOP ID - PO1			>1
N/U	140	PO1	Baseline Item Data	O	1	
N/U	160	MTX	Text	O	>1	
			LOOP ID - PPL			>1
O	170	PPL	Price Support Data	O	1	
N/U	180	REF	Reference Identification	O	>1	
			LOOP ID - PD			>1
O	190	PD	Pricing Data	O	1	
O	200	PDD	Pricing Data Detail	O	>1	
			LOOP ID - PL			>1
N/U	210	PL	Proposal Cost Logic	O	1	
N/U	220	REF	Reference Identification	O	>1	
N/U	230	AMT	Monetary Amount	O	1	
N/U	240	PCT	Percent Amounts	O	1	
N/U	250	QTY	Quantity	O	1	
N/U	260	NTE	Note/Special Instruction	O	>1	
			LOOP ID - PD			>1
N/U	270	PD	Pricing Data	O	1	
N/U	280	SPI	Specification Identifier	O	1	
N/U	290	REF	Reference Identification	O	>1	
N/U	300	PDD	Pricing Data Detail	O	>1	
N/U	310	MTX	Text	O	>1	
N/U	320	DTM	Date/Time Reference	O	10	

LOOP ID - LX					>1
O	330	LX	Assigned Number	O	1
O	340	NM1	Individual or Organizational Name	O	1
O	350	N2	Additional Name Information	O	1
O	360	N3	Address Information	O	2
O	370	N4	Geographic Location	O	1
O	375	PER	Administrative Communications Contact	O	>1
O	380	DMG	Demographic Information	O	>1
O	390	EMS	Employment Position	O	1
LOOP ID - N9					>1
O	400	N9	Reference Identification	O	1
N/U	405	L11	Business Instructions	O	>1
O	410	MTX	Text	O	>1
LOOP ID - DEG					>1
O	420	DEG	Degree Record	O	1
O	430	FOS	Field of Study	O	1
O	440	N1	Name	O	1
LOOP ID - K2					>1
N/U	450	K2	Administrative Message	O	1
N/U	460	N9	Reference Identification	O	>1
N/U	470	NM1	Individual or Organizational Name	O	>1
R	480	SE	Transaction Set Trailer	M	1

3.1 ST Segment (1/010)

Table / Position: 1 / 010

Purpose: To indicate the start of a transaction set and to assign a control number.

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	ST01	143	Transaction Set Identifier Code "194" X12.372 Grant or Assistance Application	M ID 3/3
R	ST02	329	Transaction Set Control Number	M AN 4/9

3.2 BGN Segment (1/020)

Table / Position: 1 / 020

Purpose: To indicate the beginning of a transaction set.

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	BGN01	353	Transaction Set Purpose Code "00" Original	M ID 2/2
R	BGN02	127	Reference Identification	M AN 1/30
R	BGN03	373	Date	M DT 8/8
R	BGN04	337	Time	X TM 4/8
O	BGN05	623	Time Code "LT" Local Time	O ID 2/2
O	BGN06	127	Reference Number	O ID 1/30
R	BGN07	640	Transaction Type Code "6C" Competitive Renewal "6R" Resubmission	O ID 2/2
N/U	BGN08	306	Action Code	O ID 1/2
N/U	BGN09	786	Security Level Code	O ID 2/2

3.3 PWK Segment (1/050)

Table / Position: 1 / 050

Purpose: To identify the type and transmission of paperwork or supporting information.

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	PWK01	755	Report Type Code “SD” Support Data for a Request for Quote	M ID 2/2
O	PWK02	756	Report Transmission Code “BM” By Mail “DA” Data <i>Use when transmitting the research plan as an NIH HTTP file upload. Cite “NIH File Upload” in PWK07.</i> “EL” Electronically Only <i>Use when transmitting the research plan as an X12 102 transaction set. Cite “102” in 1/N907-2/060.</i>	O ID 1/2
N/U	PWK03	757	Report Copies Needed	O NO 1/2
N/U	PWK04	98	Entity Identifier Code	O ID 2/3
N/U	PWK05	66	Identification Code Qualifier	X ID 1/2
N/U	PWK06	67	Identification Code	X AN 2/80
O	PWK07	352	Description	O AN 1/80
N/U	PWK08	C002	Actions Indicated	O
N/U	PWK09	1525	Request Category Code	O ID 1/2

3.4 N9 Segment (1/060)

Table / Position: 1 / 060

Purpose: To transmit identifying numbers and descriptive information as specified by the reference number qualifier.

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	N901	128	Reference Number Qualifier “4W” Study “6M” Application Number “CT” Contract Number “KS” Solicitation <i>If an RFA title is cited, the corresponding RFA number must also be cited in 1/BGN06/020.</i> “L4” Proposed Paragraph Number “TN” Transaction Reference Number	M ID 2/3
C	N902	127	Reference Number “J.1” Beginning Investigator	X AN 1/30
C	N903	369	Free-form Description	X AN 1/45
N/U	N904	373	Date	O DT 8/8
N/U	N905	337	Time	X TM 4/8
N/U	N906	623	Time Code	O ID 2/2
O	N907	C040	Reference Identifier	O
R	C04001	128	Reference Identifier Qualifier “7U” Related Transaction Reference Number	M ID 2/3
R	C04002	127	Reference Identification “102”	M AN 1/30

3.5 MTX Segment (1/080)

Table / Position: 1 / 080

Purpose: To specify textual data.

Usage	Ref. Des.	Data Elmt	Name	Attributes
N/U	MTX01	363	Note Reference Code	O ID 3/3
R	MTX02	1551	Message Text <i>Maximum length for an NIH project title is 81 characters.</i>	X AN 1/4096
N/U	MTX03	1551	Message Text	O AN 1/4096
N/U	MTX04	934	Printer Carriage Control Code	O ID 2/2

3.6 NMI Segment (1/090)

Table / Position: 1 / 090

Purpose: To supply the full name of an individual or organizational entity.

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	NM101	98	Entity Identifier Code “1B” Applicant “AD” Party to be advised “AZ” Previous Name “BY” Buying Party “FA” Facility “SE” Selling Party	M ID 2/3
R	NM102	1065	Entity Type Qualifier “1” Person “2” Non-person Entity	M ID 1/1
O	NM103	1035	Name Last or Organization Name <i>Maximum length for last name is 30 characters.</i>	O AN 1/35
O	NM104	1036	Name First	O AN 1/25
O	NM105	1037	Name Middle	O AN 1/25
O	NM106	1038	Name Prefix	O AN 1/10
O	NM107	1039	Name Suffix <i>Maximum length for name suffix is 5 characters.</i>	O AN 1/10
C	NM108	66	Identification Code Qualifier “1” DUNS Number, Dun & Bradstreet “9” DUNS+4, DUNS Number with Four Character Suffix	X ID 1/2
C	NM109	67	Identification Code	X AN 2/80
N/U	NM110	706	Entity Relationship Code	X ID 2/2
N/U	NM111	98	Entity Identifier Code	O ID 2/3

3.7 N2 Segment (1/100)

Table / Position: 1 / 100

Purpose: To specify additional names or names longer than 35 characters in length.

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	N201	93	Address Information <i>Use with NM103 to specify an organization name that is longer than 35 characters. Maximum length for NM103 + N201 is 40 characters.</i>	M AN 1/60
N/U	N202	93	Address Information	O AN 1/60

3.8 N3 Segment (1/110)

Table / Position: 1 / 110

Purpose: To specify the location of the named party.

Usage	Ref. Des.	ID	Name	Attributes
R	N301	166	Address Information	M AN 1/55
O	N302	166	Address Information	O AN 1/55

3.9 N4 Segment (1/120)

Table / Position: 1 / 120

Purpose: To specify the geographic location of the named party.

Usage	Ref. Des.	Data Elmt	Name	Attributes
O	N401	19	City Name	O AN 2/30
O	N402	156	State or Province Code	O ID 2/2
O	N403	116	Postal Code <i>Maximum length for postal code is 9 characters.</i>	O ID 3/15
O	N404	26	Country Code	O ID 2/3
C	N405	309	Location Qualifier "CY" County/Parish	X ID 1/2
O	N406	310	Location Identifier	O AN 1/30

3.10 N9 Segment (1/130)

Table / Position: 1 / 130

Purpose: To transmit identifying numbers and descriptive information as specified by the reference number qualifier.

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	N901	128	Reference Number Qualifier “5C” Congressional District “CR” Customer Reference Number. “EI” Employer’s Identification Number. “JD” User Identification. “P5” Position Code.	M ID 2/3
C	N902	127	Reference Number	X AN 1/30
C	N903	369	Free-form Description <i>Maximum length of a position title is 40 characters.</i>	X AN 1/45
N/U	N904	373	Date	O DT 8/8
N/U	N905	337	Time	X TM 4/8
N/U	N906	623	Time Code	O ID 2/2
N/U	N907	C040	Reference Identifier	O

3.11 PER Segment (1/140)

Table / Position: 1 / 140

Purpose: To identify a person or office to which administrative communications should be directed.

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	PER01	366	Contact Function Code “IC” Information Contact.	M ID 2/2
O	PER02	93	Name	O AN 1/60
C	PER03	365	Communication Number Qualifier “TE” Telephone	X ID 2/2
C	PER04	364	Communication Number <i>Maximum length for telephone number is 25 characters.</i>	X AN 1/80
C	PER05	365	Communication Number Qualifier “FX” Facsimile	X ID 2/2
C	PER06	364	Communication Number <i>Maximum length for facsimile number is 25 characters.</i>	X AN 1/80
C	PER07	365	Communication Number Qualifier “EM” Electronic Mail	X ID 2/2
C	PER08	364	Communication Number	X AN 1/80
O	PER09	443	Contact Inquiry Reference	O AN 1/20

3.12 HL Segment (2/010)

Table / Position: 2 / 010

Purpose: To identify dependencies among the content of hierarchically related groups of data segments.

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	HL01	628	Hierarchical ID Number	M AN 1/12
O	HL02	734	Hierarchical Parent ID Number	O AN 1/12
R	HL03	735	Hierarchical Level Code “26” Member “OS” Other Support “PC” Project Code	M ID 1/2
O	HL04	736	Hierarchical Child Code “0” No Subordinate HL Segment in This Hierarchical Structure “1” Additional Subordinate HL Segments in This Hierarchical Structure	O ID 1/1

3.13 QTY Segment (2/020)

Table / Position: 2 / 020

Purpose: To specify quantity information.

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	QTY01	673	Quantity Qualifier “37” Work In Process	M ID 2/2
R	QTY02	380	Quantity	X R 1/15
N/U	QTY03	C001	Composite Unit of Measure	O
N/U	QTY04	61	Free-Form Message	X AN 1/30

3.14 DTM Segment (2/050)

Table / Position: 2 / 050

Purpose: To specify pertinent dates and times.

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	DTM01	374	Date/Time Qualifier “193” Period Start. “194” Period End.	M ID 3/3
R	DTM02	373	Date	X DT 8/8
N/U	DTM03	337	Time	X TM 4/8
N/U	DTM04	623	Time Code	O ID 2/2
N/U	DTM05	1250	Date Time Period Format Qualifier	X ID 2/3
N/U	DTM06	1251	Date Time Period	X AN 1/35

3.15 PAM Segment (2/060)

Table / Position: 2 / 060

Purpose: To indicate a quantity and/or amount for an identified period.

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	PAM01	673	Quantity Qualifier “37” Work In Progress “A3” Most Likely Duration	X ID 2/2
R	PAM02	380	Quantity	X R 1/15
R	PAM03	C001	Composite Unit of Measure	X
R	C00101	355	Unit or Basis for Measurement Code “MO” Months	M ID 2/2
C	PAM04	522	Amount Qualifier Code “F” Annual Limit.	X ID 1/3
C	PAM05	782	Monetary Amount	X R 1/18
C	PAM06	344	Unit of Time Period or Interval “CC” Cycles	X ID 2/2
C	PAM07	374	Date/Time Qualifier “193” Period Start	X ID 3/3
C	PAM08	373	Date	X DT 8/8
N/U	PAM09	337	Time	X TM 4/8
C	PAM10	374	Date/Time Qualifier “194” Period End	X ID 3/3
C	PAM11	373	Date	X DT 8/8
N/U	PAM12	337	Time	X TM 4/8
C	PAM13	1004	Percent Qualifier “14” Availability Factor	X ID 1/2
C	PAM14	954	Percent	X R 1/10
N/U	PAM15	1073	Yes/No Condition or Response Code	O ID 1/1

3.16 NXI Segment (2/080)

Table / Position: 2 / 080

Purpose: To define the attributes of a property or an entity.

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	NX101	98	Entity Identifier Code “21” Small Business (For Profit – Small Business) “2F” State (Public - State). “2R” Federal Facility (Public – Federal). “A8” Nonprofit Institution (Private Nonprofit). “B9” Large Business (For Profit – General). “C6” Municipality (Public - Local). <i>A maximum of 1 organization type is permitted per organization.</i>	M ID 2/3
N/U	NX102	98	Entity Identifier Code	O ID 2/3
N/U	NX103	98	Entity Identifier Code	O ID 2/3
N/U	NX104	98	Entity Identifier Code	O ID 2/3
N/U	NX105	98	Entity Identifier Code	O ID 2/3

3.17 YNQ Segment (2/090)

Table / Position: 2 / 090

Purpose: To identify and answer yes and no questions, including the date, time, and comments further qualifying the condition.

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	YNQ01	1321	Condition Indicator “H0” Organization Certifies Compliance With Federal Lobbying Regulations “H4” Lobbying Activities Have Been Conducted Regarding the Proposal “H5” Organization Certifies Compliance With the Drug-Free Workplace Act “H6” Organization Certifies Compliance With the Code of Federal Regulations Regarding Research Misconduct “H7” Organization Provides a Smoke Free Workplace “H8” Organization Certifies Compliance With Federal Discrimination Regulations “H9” Organization Certifies Compliance With the Code of Federal Regulations Regarding Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service (PHS) Funding is Sought “I7” Organization has Delinquent Federal Debts “I8” Organization Has Been Placed on the Federal Debarment and Suspension List	X ID 2/2
R	YNQ02	1073	Yes/No Condition or Response Code “N” No “Y” Yes	M ID 1/1
N/U	YNQ03	1250	Date Time Period Format Qualifier	X ID 2/3
N/U	YNQ04	1251	Date Time Period	X AN 1/35
O	YNQ05	933	Free-Form Message Text	O AN 1/264
O	YNQ06	933	Free-Form Message Text	O AN 1/264
O	YNQ07	933	Free-Form Message Text	O AN 1/264
N/U	YNQ08	1270	Code List Qualifier Code	C ID 1/3
N/U	YNQ09	1271	Industry Code	C AN 1/30
N/U	YNQ10	933	Free-Form Message Text	O AN 1/264

3.18 N9 Reference Identification (2/100)

Table / Position: 2 / 100

Purpose: To transmit identifying information as specified by the Reference Identification Qualifier.

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	N901	128	Reference Number Qualifier "43" Supporting Document Number. "F4" Facility Certification Number. "L4" Proposal Paragraph Number. "WT" Waiver. "Y9" Current Certificate Number.	M ID 2/3
C	N902	127	Reference Number "A" Abstract "B.2" Aims "C.1" Personnel & Budget Justifications "C.2" Space/Facilities "C.3" Equipment "E.4" Program Related Income "E.7" Indirect Cost Base "F.2" Cover Letter "I.6" Inventions	X AN 1/30
C	N903	369	Free-form Description	X AN 1/45
O	N904	373	Date	O DT 8/8
N/U	N905	337	Time	X TM 4/8
N/U	N906	623	Time Code	O ID 2/2
N/U	N907	C040	Reference Identification	O

3.19 MTX Segment (2/110)

Table / Position: 2 / 110

Purpose: To specify textual data.

Usage	Ref. Des.	Data Elmt	Name	Attributes
N/U	MTX01	363	Note Reference Code	O ID 3/3
R	MTX02	1551	<p>Message Text</p> <p><i>Maximum length for the Gender and Minority Inclusion title is 60 characters.</i></p> <p><i>Maximum length for the abstract and research plan specific aims is 2G.</i></p> <p><i>Maximum length for the budget justification is 2K.</i></p> <p><i>Maximum length for space/facilities is ???</i></p> <p><i>Maximum length for equipment is ???</i></p> <p><i>Maximum length for program related income is 100 characters.</i></p> <p><i>Maximum length for indirect cost base explanation is 2G.</i></p> <p><i>Maximum length for the cover letter is ???</i></p> <p><i>When N902 is code I.6, cite the word REPORTED if the invention/patent was previously reported. Provide no further information.</i></p>	X AN 1/4096
O	MTX03	1551	Message Text	O AN 1/4096
N/U	MTX04	934	Printer Carriage Control Code	O ID 2/2

3.20 INX Segment (2/120)

Table / Position: 2 / 120

Purpose: To specify an index.

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	INX01	1550	Index Qualifier "1" Matrix Start – Absolute Reference	M ID 1/2
R	INX02	C036	Index Identification	M
O	C03601	1395	Configuration Type Code "1" Horizontal, Left to Right <i>Construct the Gender and Minority Inclusion matrix as follows: Rows: 1 (Male), 2 (Female), 3 (Unknown) Cols: A (Indian), B (Asian), C (Black), D (Hispanic), E (White), F (Other)</i>	O ID 1/1
C	C03602	127	Reference Identification	X AN 1/30
C	C03603	127	Reference Identification	X AN 1/30
N/U	C03604	863	X-Peg	X R 1/6
N/U	C03605	864	Y-Peg	X R 1/6

3.21 K3 Segment (2/130)

Table / Position: 2 / 130

Purpose: To transmit fixed-format record or matrix contents.

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	K301	449	Fixed Format Information	M AN 1/80
N/U	K302	1333	Record Format Code	O ID 1/2
N/U	K303	C001	Unit or Basis for Measurement Code	O

3.22 PPL Segment (2/170)

Table / Position: 2 / 170

Purpose: To provide information about pricing support.

Usage	Ref. Des.	Data Elmt	Name	Attributes
N/U	PPL01	1309	Acquisition Data Code	O ID 2/2
N/U	PPL02	373	Date	O DT 8/8
N/U	PPL03	373	Date	O DT 8/8
O	PPL04	352	Description	O AN 1/80
N/U	PPL05	1401	Proposal Data Detail Identifier Code	O ID 1/3

3.23 PD Segment (2/190)

Table / Position: 2 / 190

Purpose: To describe the pricing basic input detail.

Notes:

1. *This Implementation Guide mandates the following method for specifying a labor category comprising multiple persons:*

- *Set PD08 to the numeric value of “1”, use PD09 to identify the labor category, and repeat this process for the total of persons in the labor category.*

If, for example, a labor category comprises six nurses: set PD08 to the numeric value of 1, set PD09 to the value of “NURSE”, and repeat this process for a total of six iterations.

2. *For individuals with different percentages over different periods (e.g., different level of effort for academic period verses summer period), use only one iteration of the PD loop and average the percentages for the individual.*

3. *All people specified for an application must be identified in the budget.*

4. *To specify Facilities and Administration Costs, set PD07 to the appropriate code that identifies the Indirect Cost Base (i.e., 08, 47, 51, or ZZ). Alternately, set PD07 to code 09 and specify the Indirect Cost Base in a separate iteration of the PD loop.*

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	PD01	344	Unit of Time Period or Interval “AP” Academic Period “CC” Cycles “CY” Calendar Year “SP” Summer Period	M ID 2/2
R	PD02	373	Date	M DT 8/8
R	PD03	C001	Composite Unit of Measure	M
R	C00101	355	Unit or Basis for Measurement Code “DO” Dollars, U.S. “P1” Percent. <i>To specify multiple Indirect Cost Rates for a budget period, either average the rates and bases and provide the averaged values or specify each rate and base value individually. Providing an explanation is recommended.</i>	M ID 2/2
O	C00104	355	Unit or Basis for Measurement Code “8S” Session.	O ID 2/2
R	PD04	380	Quantity	M R 1/15
R	PD05	93	Name	M AN 1/60
O	PD06	352	Description	O AN 1/80
O	PD07	1196	Breakdown Structure Detail Code “01” Labor. “03” Other Direct Costs. <i>NIH calculates this field; i.e., NIH ignores submitted values.</i> “08” Other Overhead. “09” Total Overhead. “38” Total Cost Plus General and Administrative. “39” Other Costs. <i>Include tuition remission costs under Other Costs.</i> “42” Purchased Equipment. “43” Materials and Purchased Items. “46” Commercial Effort. “47” Total Direct Cost Base. “48” Indirect Labor. “49” Employee Benefits. “51” Employment. “52” Communications and Travel. “70” Total Salary and Wages. “71” Total Salary and Wages and Employee Benefits. “72” Total Purchased Equipment. “80” Publication Costs. “81” Consultant Services. “82” ADP Services. “84” Total Direct Costs. “85” Human Subject Costs. “86” Animal Costs. “87” Alterations and Renovations. “BL” Billings. “EH” Equipment Maintenance. “RL” Rental or Lease of Equipment or Facilities. “ZZ” Mutually Defined.	O ID 2/2

O	PD08	127	Reference Identification <i>If PD09 identifies a labor category, cite the number "1" to indicate one FTE.</i> <i>For a named individual, use the syntax: LastName, FirstName, MiddleName</i>	O AN 1/30
O	PD09	352	Description <i>Maximum length constraint for a project role or labor category is 30 characters.</i> <i>NIH recognizes the following project roles: Principal Investigator, Research Assistant, Staff Scientist, Fellow, Lab Technician, and Supportee.</i>	O AN 1/80
N/U	PD10	1401	Proposed Data Detail Identifier Code	O ID 1/3

3.24 PDD Segment (2/200)

Table / Position: 2 / 200

Purpose: To provide the rates, direct input, and pricing factors for each element of work, cross-referenced to an applicable request or submission.

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	PDD01	350	Assignment Identification	M AN 1/20
O	PDD02	380	Quantity	X R 1/15
O	PDD03	782	Monetary Amount <i>Monetary amounts must be an integer value of no more than 10 digits.</i> <i>When identifying an individual's salary, and the person is requesting no salary, cite a value of "0".</i>	X R 1/18
C	PDD04	954	Percent	X R 1/10
N/U	PDD05	1401	Proposal Data Detail Identifier Code	O ID 1/3

3.25 LX Segment (2/330)

Table / Position: 2 / 330

Purpose: To reference a line number in a transaction set.

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	LX01	554	Assigned Number	M NO 1/6

3.26 NMI Segment (2/340)

Table / Position: 2 / 340

Purpose: To supply the full name of an individual or organizational entity.

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	NM101	98	Entity Identifier Code “61” Performed At. “92” Support Party. “9K” Key Person. “9P” Investigator. “K8” Filing Location.	M ID 2/3
R	NM102	1065	Entity Type Qualifier “1” Person. “2” Non-person Entity.	M ID 1/1
O	NM103	1035	Name Last or Organization Name <i>Maximum length for last name is 30 characters</i> <i>When specifying the Other Support PI name, the total characters comprising NM103 through NM107 must be no more than 60 characters.</i>	O AN 1/35
O	NM104	1036	Name First	O AN 1/25
O	NM105	1037	Name Middle	O AN 1/25
O	NM106	1038	Name Prefix	O AN 1/10
O	NM107	1039	Name Suffix <i>Maximum length for name suffix is 5 characters.</i>	O AN 1/10
N/U	NM108	66	Identification Code Qualifier	X ID 1/2
N/U	NM109	67	Identification Code	X AN 2/80
N/U	NM110	706	Entity Relationship Code	X ID 2/2
N/U	NM11	98	Entity Identifier Code	O ID 2/3

3.27 N2 Segment (2/350)

Table / Position: 2 / 350

Purpose: To specify additional names or names longer than 35 characters in length.

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	N201	93	Address Information <i>Use with NM103 to specify an organization name that is longer than 35 characters. Maximum length for an organization name is 40 characters.</i>	M AN 1/60
N/U	N202	93	Address Information	O AN 1/60

3.28 N3 Segment (2/360)

Table / Position: 2 / 360

Purpose: To specify the location of the named party.

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	N301	166	Address Information	M AN 1/55
O	N302	166	Address Information	O AN 1/55

3.29 N4 Segment (2/370)

Table / Position: 2 / 370

Purpose: To specify the geographic location of the named party.

Usage	Ref. Des.	Data Elmt	Name	Attributes
O	N401	19	City Name	O AN 2/30
O	N402	156	State or Province Code	O ID 2/2
O	N403	116	Postal Code <i>Maximum length for Postal Code is 9 characters.</i>	O ID 3/15
O	N404	26	Country Code	O ID 2/3
O	N405	309	Location Qualifier "CY" County/Parish	X ID 1/2
O	N406	310	Location Identifier	O AN 1/30

3.30 PER Segment (2/375)

Table / Position: 2 / 375

Purpose: To identify a person or office to which administrative communications should be directed.

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	PER01	366	Contact Function Code "IC" Information Contact.	M ID 2/2
N/U	PER02	93	Name	O AN 1/60
R	PER03	365	Communication Number Qualifier "TE" Telephone.	X ID 2/2
R	PER04	364	Communication Number <i>Maximum length for telephone number is 25 characters.</i>	X AN 1/80
C	PER05	365	Communication Number Qualifier "FX" Facsimile.	X ID 2/2
C	PER06	364	Communication Number <i>Maximum length for facsimile number is 25 characters.</i>	X AN 1/80
C	PER07	365	Communication Number Qualifier "EM" Electronic Mail.	X ID 2/2
C	PER08	364	Communication Number	X AN 1/80
O	PER09	443	Contact Inquiry Reference	O AN 1/20

3.31 DMG Segment (2/380)

Table / Position: 2 / 380

Purpose: To supply demographic information.

Usage	Ref. Des.	Data Elmt	Name	Attributes
N/U	DMG01	1250	Date Time Period Format Qualifier	C ID 2/3
O	DMG02	1251	Date Time Period	C AN 1/35
O	DMG03	1068	Gender Code “A” Not Provided. “F” Female. “M” Male.	O ID 1/1
N/U	DMG04	1067	Marital Status Code	O ID 1/1
O	DMG05	1109	Race or Ethnicity Code “7” Not Provided. “A” Asian “B” Black “C” Caucasian “H” Hispanic “I” American Indian or Alaskan Native “P” Pacific Islander	O ID 1/1
O	DMG06	1066	Citizenship Status Code	O ID 1/2
N/U	DMG07	26	Country Code	O ID 2/3
N/U	DMG08	659	Basis of Verification Code	O ID 1/2
N/U	DMG09	380	Quantity	O R 1/15

3.32 EMS Segment (2/390)

Table / Position: 2 / 390

Purpose: To describe employment position.

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	EMS01	352	Description <i>Maximum length for project role is 30 characters.</i> <i>NIH recognizes the following project roles: Research Assistant, Staff Scientist, Fellow, Lab Technician, Supportee</i>	M AN 1/80
N/U	EMS02	1176	Employment Class Code	O ID 2/3
N/U	EMS03	1149	Occupation Code	O ID 4/6
N/U	EMS04	584	Employment Status Code	O ID 2/2
N/U	EMS05	128	Reference Number Qualifier	X ID 2/3
N/U	EMS06	127	Reference Number	X AN 1/30
N/U	EMS07	127	Reference Number	O AN 1/30

3.33 N9 Segment (2/400)

Table / Position: 2 / 400

Purpose: To transmit identifying numbers and descriptive information as specified by the reference number qualifier.

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	N901	128	Reference Number Qualifier "19" Division Identifier. "AH" Agreement Number. "BD" Bid Number. "CT" Contract Number. "JD" User Identification. "K5" Task Order. "L4" Proposal Paragraph Number. "P5" Position Code. "SY" Social Security Number. "YV" Participating Area. <i>Summarize overlap for all OS projects on a per individual basis.</i>	M ID 2/3
C	N902	127	Reference Identification "D" Biographical <i>Code "D" is mutually exclusive from codes "D.1", "D.2", "D.3", and "D.4".</i> "D.1" Experience "D.2" Employment History "D.3" Honors "D.4" Memberships/Associations "D.5" Publications "D.5.1" Medline Accession Number	X AN 1/30
C	N903	369	Free-form Description <i>Maximum length of a position title is 40 characters..</i>	X AN 1/45
O	N904	373	Date	O DT 8/8
N/U	N905	337	Time	X TM 4/8
N/U	N906	623	Time Code	O ID 2/2
O	N907	C040	Reference Identifier	O
R	C04001	128	Reference Identification Qualifier "DP" Department Number.	M ID 2/3
R	C04002	127	Reference Identification	M AN 1/30

3.34 MTX Segment (2/410)

Table / Position: 2 / 410

Purpose: To specify textual data.

Usage	Ref. Des.	Data Elmt	Name	Attributes
N/U	MTX01	363	Note Reference Code	O ID 3/3
R	MTX02	1551	<p>Message Text</p> <p><i>Maximum length for the Other Support project title is 60 characters.</i></p> <p><i>Maximum length for the Other Support major goals is 700 characters.</i></p> <p><i>Maximum length for the Other Support overlap is 700 characters.</i></p> <p><i>Maximum length for Biographical data is 2G.</i></p> <p><i>Maximum length for Publications (text) is 2G.</i></p>	X AN 1/4096
O	MTX03	1551	Message Text	O AN 1/4096
N/U	MTX04	934	Printer Carriage Control Code	O ID 2/2

3.35 DEG Segment (2/420)

Table / Position: 2 / 420

Purpose: To provide the receiving institution or agency notice of academic awards made to the student whose record is being transmitted.

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	DEG01	1126	Academic Degree Code <i>This information is not captured by NIH.</i>	M ID 3/3
R	DEG02	1250	Date Time Period Format Qualifier "CM" Date in Format CCYYMM	X ID 2/3
R	DEG03	1251	Date Time Period	X AN 1/35
R	DEG04	352	Description <i>Select degrees from list below.</i>	O AN 1/80
N/U	DEG05	641	Status Reason Code	O ID 3/3

AB	CHB	DNS	LLB	MLS	OD
AS	DC	DNSC	LLD	MN	PHB
BA	DDS	DO	LLM	MPH	PHD
BCH	DED	DPH	MA	MPHN	PHRM
BD	DENG	DSC	MB	MPM	RN
BENG	DHS	DSN	MBBS	MRCP	SCD
BM	DLS	DSW	MCHD	MS	VMD
BS	DMD	DVM	MCHR	MSCD	OTH (other)
BSD	DMS	DVS	MD	MSD	
BSN	DMSC	EDD	MDS	MSN	
BSNE	DN	HS	MEDS	MSNE	
BSW	DNED	JD	MENG	MSW	

3.36 FOS Segment (2/430)

Table / Position: 2 / 430

Purpose: To provide the receiving institution or agency with information about the field of study associated with the academic awards made to the student whose record is being transmitted.

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	FOS01	1153	Academic Field of Study Level or Type Code “M” Major	M ID 1/1
N/U	FOS02	66	Identification Code Qualifier	X ID 1/2
N/U	FOS03	67	Identification Code	X AN 2/80
R	FOS04	352	Description <i>Only one area of study can be specified per degree.</i>	O AN 1/80
O	FOS05	352	Description <i>Only one area of specialization can be specified per degree.</i>	O AN 1/80
N/U	FOS06	380	Quantity	O R 1/15
N/U	FOS07	380	Quantity	O R 1/15

3.37 N1 Segment (2/440)

Table / Position: 2 / 440

Purpose: To identify a party by type of organization, name, and code.

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	N101	98	Entity Identifier Code “1R” University, College, or School	M ID 2/3
R	N102	93	Name	X AN 1/60
N/U	N103	66	Identification Code Qualifier	X ID 1/2
N/U	N104	67	Identification Code	X AN 2/80
N/U	N105	706	Entity Relationship Code	O ID 2/2
N/U	N106	98	Entity Identifier Code	O ID 2/3

3.38 SE Segment (2/480)

Table / Position: 2 / 480

Purpose: To indicate the end of the transaction set and provide the count of the transmitted segments (including the beginning (ST) and ending (SE) segments).

Usage	Ref. Des.	Data Elmt	Name	Attributes
R	SE01	96	Number of Included Segments	M NO 1/10
R	SE02	329	Transaction Set Control Number	M AN 4/9

Appendix A. Sample PHS 398 Application and 194 Transaction Set

This appendix contains a sample PHS 398 application. The sample application is followed by the corresponding X12 194 transaction set.

The sample PHS 398 application contains fictitious information. Although the application data is *realistic* in format, it should not be used as guidance for completing a 398 application. The purpose of the sample application is to illustrate the relationship between 398 form data elements and X12 194 data elements.

Also, note that within the transaction set certain data elements are italic and bold. These data elements are mapped directly to fields in an NIH database.

Department of Health and Human Services Public Health Services <h2 style="text-align: center;">Grant Application</h2> <i>Follow instructions carefully. Do not exceed character length restrictions indicated on sample.</i>		LEAVE BLANK—FOR PHS USE ONLY.			
		Type	Activity	Number	
		Review Group		Formerly	
		Council/Board (Month, Year)		Date Received	
1. TITLE OF PROJECT (Do not exceed 56 characters, including spaces and punctuation.) Atherosclerosis Prevention Study					
2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT x NO YES (If "Yes," state number and title) Number: Title:					
3. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR			New Investigator <input checked="" type="checkbox"/> YES		
3a. NAME (Last, first, middle) Galilei, Galileo, N.		3b. DEGREE(S) B.S., M.D.		3c. SOCIAL SECURITY NO. <i>Provide on Form Page KK.</i>	
3d. POSITION TITLE Professor of Medicine		3e. MAILING ADDRESS (Street, city, state, zip code) University of Bethesda Atherosclerosis Research Unit 461 Ocean Blvd., MSC-32 Bethesda, MD 20892 E-MAIL ADDRESS: ggalileo@ub.edu			
3f. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT MDK					
3g. MAJOR SUBDIVISION 01					
3h. TELEPHONE AND FAX (Area code, number and extension) TEL: (301) 555 1478 FAX: (301) 555 2685					
4. HUMAN SUBJECTS		4a. If "Yes," Exemption no. <u>or</u> IRB approval date <input type="checkbox"/> Full IRB <u>or</u> Expedited Review		4b. Assurance of compliance no. M123456XB	
No x Yes		Pending <input type="checkbox"/>		5. VERTEBRATE ANIMALS No x Yes	
				5a. If "Yes," IACUC approval date 02/01/97	
				5b. Animal welfare assurance no. A9999-01	
6. DATES OF PROPOSED PERIOD OF SUPPORT (month, day, year—MM/DD/YY) From 04/01/98 Through 03/31/00		7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD 7a. Direct Costs (\$) \$470,757		8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT 8a. Direct Costs (\$) \$1,098,404 8b. Total Costs (\$) \$1,664,082	
9. APPLICANT ORGANIZATION Name University of Bethesda Address 461 Ocean Blvd. Bethesda, MD 20892 IPF # 1234567 DUNS # 112233445		10. TYPE OF ORGANIZATION Public: <input checked="" type="radio"/> Federal State Local Private: <input checked="" type="radio"/> x Private Nonprofit Forprofit: <input checked="" type="radio"/> General Small Business			
		11. ORGANIZATIONAL COMPONENT CODE 01			
		12. ENTITY IDENTIFICATION NUMBER 0123454321A1		Congressional District	
13. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE Name Tycho H. Brahe Title Deputy Director Address Dept of Contracts and Grants 1313 Mockingbird Lane, DEI-5555 Bethesda, MD 20892 Telephone (301) 555 2396 FAX (301) 555 2835 E-Mail tbrahe@munster.ub.edu Address		14. OFFICIAL SIGNING FOR APPLICATION ORGANIZATION Name Giordano Bruno Jr. Title Provost & Senior VP for Academic Affairs Address Dept of Contracts and Grants 1313 Mockingbird Lane, DEI-5555 Bethesda, MD 20892 Phone (301) 555 2396 FAX (301) 555 2835 E-Mail giordano.bruno@ub.edu Address			
15. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.		SIGNATURE OF PI/PD NAMED IN 3a. (In ink. "Per" signature not acceptable.)		DATE 06/02/97	
16. APPLICATION ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.		SIGNATURE OF OFFICIAL NAMED IN 14. (In ink. "Per" signature not acceptable.)		DATE 06/02/97	

DESCRIPTION: State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project. Describe concisely the research design and methods for achieving these goals. Avoid summaries of past accomplishments and the use of the first person. This abstract is meant to serve as a succinct and accurate description of the proposed work when separated from the application. If the application is funded, this description, as is, will become public information. Therefore, do not include proprietary/confidential information. **DO NOT EXCEED THE SPACE PROVIDED.**

This is where the abstract would go.

PERFORMANCE SITE(S) (*organization, city, state*)

Pharmacology Research Laboratory, Bethesda, MD

KEY PERSONNEL. See instructions on Page 11. *Use continuation pages as needed* to provide the required information in the format shown below.

Name	Organization	Role on Project
Galilei, Galileo	University of Bethesda	Principal Investigator
Copernicus, Nicholas	University of Bethesda	Research Assistant
Newton, Isaac	University of Bethesda	Staff Scientist

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY					FROM 04/01/98	THROUGH 03/31/99	
PERSONNEL (Applicant organization only)		TYPE APPT. (months)	% EFFORT ON PROJ.	INST. BASE SALARY	DOLLAR AMOUNT REQUESTED (omit cents)		
NAME	ROLE ON PROJECT				SALARY REQUESTED	FRINGE BENEFITS	TOTAL
Galilei, Galileo	Principal Investigator	12	40	\$110,000	\$44,000	\$13,772	\$57,772
Copernicus, Nicholas	Research Assistant	9	20	\$119,719	\$11,972	\$3,747	\$15,719
Copernicus, Nicholas	Research Assistant	2	100	\$119,719	\$26,602	\$8,326	\$34,928
Newton, Isaac	Staff Scientist	12	10	\$125,000	\$0	\$0	\$0
Keplar, Johannes	Supportee	12	50	\$25,331	\$12,666	\$3,964	\$16,630
TBD	Supportee	12	100	\$35,000	\$35,000	\$10,955	\$45,955
TBD	Lab Technician	12	100	\$32,000	\$32,000	\$9,600	\$41,600
TBD	Lab Technician	12	100	\$36,000	\$36,000	\$10,800	\$46,800
SUBTOTALS					\$198,240	\$61,164	\$259,404
CONSULTANT COSTS							\$22,400
EQUIPMENT (Itemize) Single cell Perfusion Chambers and Filter Sets \$5,500 Centrifuge \$15,000							\$20,500
SUPPLIES (Itemize by category) Office, postage, and xerographical supplies for Clinic, Biostatistical, and Administrative components \$4000 Lipid Laboratory supplies \$1400							\$5,400
TRAVEL Travel to National meetings for 3 individuals							\$4,000
PATIENT CARE COSTS		INPATIENT					\$3,500
		OUTPATIENT					\$84,720
ALTERATIONS AND RENOVATIONS (Itemize by category)							\$28,750
OTHER EXPENSES (Itemize by category) Equipment Maintenance \$1,183; Publication Costs \$1,500; Animal Costs \$4,400; Other Expenses \$35,000							\$42,083
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD					\$	\$470,757	
CONSORTIUM/CONTRACTUAL COSTS		DIRECT COSTS					
		INDIRECT COSTS					
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD (Item 7a, Face Page)					\$	\$470,757	

**BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD
DIRECT COSTS ONLY**

BUDGET CATEGORY TOTALS		INITIAL BUDGET PERIOD (from Form Page 4)	ADDITIONAL YEARS OF SUPPORT REQUESTED			
			2nd	3rd	4th	5th
PERSONNEL: <i>Salary and fringe benefits Applicant organization only</i>		\$259,404	\$465,898			
CONSULTANT COSTS		\$22,400	\$23,296			
EQUIPMENT		\$20,500				
SUPPLIES		\$5,400	\$5,616			
TRAVEL		\$4,000	\$4,098			
PATIENT CARE COSTS	INPATIENT	\$3,500				
	OUTPATIENT	\$84,720	\$87,648			
ALTERATIONS AND RENOVATIONS		\$28,750				
OTHER EXPENSES		\$42,083	\$41,091			
SUBTOTAL DIRECT COSTS		\$470,757	\$627,647			
CONSORTIUM/ CONTRACTUAL COSTS	DIRECT					
	INDIRECT					
TOTAL DIRECT COSTS		\$470,757	\$627,647			

TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD (Item 8a, Face Page) _____

\$ 1,098,404

JUSTIFICATION. Follow the budget justification instructions exactly. Use continuation pages as needed.
This is where the budget justification would go.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed for Form Page 2.
Photocopy this page or follow this format for each person.

NAME		POSITION TITLE	
Galilei, Galileo		Professor of Medicine	
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
University of Northern Italy	BS	1959	Medicinal Chemistry
University of Pisa	MD	1963	Medicine

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list, in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. If the list of publications in the last three years exceeds two pages, select the most pertinent publications. **DO NOT EXCEED TWO PAGES.**

Experience:

1963-1965: University of California, Los Angeles. Department: Medicine. Resident.
 1965-1974: University of California, Los Angeles. Department: Medicine. Medical Resident.
 1974-1979: University of California, Los Angeles. Department: Medicine. Chief Resident.
 1979-1992: University of California, San Diego. Department: Medicine. Associate Professor of Medicine.
 1992-1997: University of Bethesda. Department: Medicine. Professor of Medicine.

Honors:

Years: 1994-1995 JM Osbourne Preventive Medicine Award
 Years: 1995-1996 American Society for Immunology Travel Award

Memberships:

Federal Advisory Committee Membership.
 Agency: NIDDK Title: GMA-2 Study Section Start Year: 01/01/93 End Year: 01/01/1997

Publications:

- Galilei, G., Brown C (1997). The pathogenesis of coronary disease. New England Journal of Medicine, 236: 142-150.
- Galilei, G., Robin, C. (1995). Triggering of plaque disruption. Circulation, 81: 576-584.
- Galilei, G., Dilbert D. (1995) Arterial imaging and atherosclerosis reversal. Arterioscler Thromb. 14: 77-92.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed for Form Page 2.
Photocopy this page or follow this format for each person.

NAME		POSITION TITLE	
Copernicus, Nicholas		Clinical Investigator	
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
University of Cracow	BS	1979	Biological Chemistry
University of Cracow	PhD	1983	Biological Chemistry

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list, in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. If the list of publications in the last three years exceeds two pages, select the most pertinent publications. **DO NOT EXCEED TWO PAGES.**

Experience:

1983-1986: National Institute of Allergy/Infectious Disease. Department: Lab of Clinical Investigation. Visiting Fellow.

1986-1992: University of Bethesda. Department: Medicine. Medical Resident.

1992-1997: University of Bethesda. Department: Medicine. Clinical Investigator.

Membership:

Agency: DRG NIH. Title: Ad hoc reviewer GMA-2 Study Section. Start year: 01/01/96

Publications:

1. Copernicus, N., Pooh W. (1997) Risk factor assessment and prevention of coronary artery disease. J Intern Med.;263:211-3.

2. Copernicus, N., McDonald R. (1997) Cholesterol Lowering Atherosclerosis Study (CLAS). Controlled Clin Trials. 18:156-87.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed for Form Page 2.
Photocopy this page or follow this format for each person.

NAME		POSITION TITLE	
Newton, Issac		Biostatistician	
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
New University College, London	BS	1975	Mathematics
New University College, London	MS	1978	Mathematics
Cambridge University	PhD	1982	Biometry

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list, in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. If the list of publications in the last three years exceeds two pages, select the most pertinent publications. **DO NOT EXCEED TWO PAGES.**

Experience:

1982-1984: Jackson Memorial Hospital, Department: Medicine. Staff Research Associate.

1984-1988: University of Illinois, Medical School. Department: Medicine. Associate Specialist.

1988-1997: University of Bethesda. Department: Medicine. Associate Professor of Biometry.

Publications:

Newton, I., Greenjeans, M. (1996) Effects of colestipol-niacin therapy on atherosclerosis. Circulation. 38:138-47.

Other Support

GALILEI, G.ACTIVE

2 R01 HL 00000-13 (Galilei)	3/1/96 - 2/28/99	30%
NIH/NHLBI	\$186,529	
Chloride and Sodium Transport in Airway Epithelial Cells		

The major goals of this project are to define the biochemistry of chloride and sodium transport in airway epithelial cells and clone the gene(s) involved in transport.

PENDING

DCB 950000 (Galilei)	12/01/98-11/30-00	20%
National Science Foundation	\$82,163	
Liposome Membrane Composition and Function		

The major goals of this project are to define biochemical properties of liposome membrane components and maximize liposome uptake into cells.

OVERLAP

There is scientific overlap between aim 2 of NSF DCB 950000 and aim 4 of the application under consideration. If both are funded, the budgets will be adjusted appropriately in conjunction with agency staff.

COPERNICUS, N.NONE**NEWTON, I.**ACTIVE

Investigator Award (Newton)	9/1/97 - 8/31/01	70%
Howard Hughes Medical Center	\$581,317	
Gene Cloning and Targeting for Neurological Disease Genes		

This award supports the PI's program to map and clone the gene(s) implicated in the development of Alzheimer's disease and to target expression of the cloned gene(s) to relevant cells.

OVERLAP

None

RESOURCES

FACILITIES: Specify the facilities to be used for the conduct of the proposed research. Indicate the performance sites and describe capabilities, pertinent capabilities, relative proximity, and extent of availability to the project. Under "Other," identify support services such as machine shop, electronics shop, and specify the extent to which they will be available to the project. Use continuation pages if necessary.

Laboratory: X

These studies will be performed in the laboratory of Dr. Galilei. Dr. Galilei's laboratory is located in the Clinical Research Center of the University of Bethesda. The laboratory contains sinks, benches, refrigerators, and freezers for in vitro studies.

Clinical: X

There is full access to patients at the Pharmacology Research Laboratory in Bethesda, MD. In addition, there is support of community physicians.

Animal: X

There are animal housing and procedure rooms in the Clinical Research Center. This facility is staffed by veterinarians and animal husbandry personnel.

Computer: X

Dr. Galilei's laboratory contains a network of Pentium PCs with two color laser printers. The network has direct access to the Internet via the University of Bethesda backbone.

Office: X

There are several offices adjacent to Dr. Galilei's laboratory with desks, bookshelves, filing cabinets and computer systems. These can be used by both investigators and administrative personnel.

Other:

N/A

MAJOR EQUIPMENT: List the most important equipment items already available for this project, noting the location and pertinent capabilities of each.

The Clinical Research Center contains the following:

Liquid scintillation counter, ultracentrifuge, refrigerated centrifuge, CO₂ incubator, radioisotope detector, microscopes, balances, and a digital imaging system with computer control and perfusion equipment.

CHECKLIST

TYPE OF APPLICATIONS (Check all that apply.)

NEW application. (This application is being submitted to the PHS for the first time.)

REVISION of application number: _____
(This application replaces a prior unfunded version of a new, competing continuation, or supplemental application.)

X COMPETING CONTINUATION of grant number: 1 R01 AI00000-01A1
(This application is to extent a funded grant beyond its current project period.)

INVENTIONS AND PATENTS (Competing continuation appl. only)

No X Previously reported
X Yes. If "Yes," Not previously reported

SUPPLEMENT to grant number: _____
(This application is for additional funds to supplement a currently funded grant.)

X CHANGE of principal investigator/program director.
Name of former principal investigator/program director: Berhard Schmidt

FOREIGN application or significant foreign component.

1. ASSURANCES/CERTIFICATIONS

The following assurances/certifications are made and verified by the signature of the Official Signing for Application Organization on the Face Page of the application. Descriptions of individual assurances/certifications begin on page 27 of Section III. If unable to certify compliance where application, provide an explanation and place it after this page.

•Human Subjects; •Vertebrate Animals; •Debarment and Suspension; •Drug- Free Workplace (application to new [Type 1] or revised [Type 1] applications only); •Lobbying; •Delinquent Federal Debt; •Research Misconduct; •Civil Rights (Form HHS 441 or HHS 690); •Handicapped Individuals (Form HHS 641 or HHS 690); •Sex Discrimination (Form HHS 639-A or HHS 690); •Age Discrimination (Form HHS 680 or HHS 690); •Financial Conflict of Interest.

2. PROGRAM INCOME (See instructions, page 20.)

All applications must indicate whether program income is anticipated during the period(s) for which grant support is request. If program income is anticipated, use the format below to reflect the amount and source(s).

Budget Period	Anticipated Amount	Source(s)
04/01/98-03/31/99	\$50,000	Howard Hughes Medical Center

3. INDIRECT COSTS

Indicate the applicant organization's most recent indirect cost rate established with the appropriate DHHS Regional Office, or, in the case of for profit organizations, the rate established with the appropriate PHS Agency Cost Advisory Office. If the applicant organization is in the process of initially developing or renegotiating a rate, or has established a rate with another Federal agency, it should, immediately upon notification that an award will be made, develop a tentative indirect cost rate proposal. This is to be based on

its most recently completed fiscal year in accordance with the principles set forth in the pertinent DHHS Guide for Establishing Indirect Cost Rates, and submitted to the appropriate DHHS Regional Office or PHS Agency Cost Advisory Office. Indirect costs will **not** be paid on foreign grants, construction grants, grants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for Research Career Awards, Institutional National Research Service Awards, and specialized grant applications.

X DHHS Agreement dated: 01/01/98 No Indirect Costs Requested.

DHHS Agreement begin negotiated with _____ Regional Office.

No DHHS Agreement, but rate established with _____ Date _____

CALCULATION* (The entire grant application, including the Checklist, will be reproduced and provided to peer reviewers as confidential information. Supplying the following information on indirect costs is optional for forprofit organizations.)

a. Initial budget period: Amount of base \$ 470,757 x Rate applied 51.50 % = Indirect costs (1) \$ 242,439

b. Entire proposed project period: Amount of base \$ 1,098,404 x Rate applied 51.50 % = Indirect costs (2) \$ 565,678

- (1) Add to total direct costs from form page 4 and enter new total on Face Page, Item 7b.
- (2) Add to total direct costs from form page 5 and enter new total on Face Page, Item 8b.

*Check appropriate box(es):

Salary and wages base X Modified total direct cost base Other base (Explain)

Off-site, other special rate, or more than one rate involved (Explain)

Explanation (Attach separate sheet, if necessary.):

4. SMOKE-FREE WORKPLACE

Does your organization currently provide a smoke-free workplace and/or promote the nonuse of tobacco products or have plans to do so?
X Yes No (The response to this question has no impact on the review or funding of this application.)

**Competing Continuation Applications
PERSONNEL REPORT**

All Personnel for the Current Budget Period

Name	Degree(s)	SSN	Role on Project (e.g. PI, Res. Assoc.)	Date of Birth (MM/DD/YY)	Annual % Effort
Galilei, Galileo	BS, MD	123-45-6789	PI	03/03/38	40
Copernicus, Nicholas	BS, PhD		Research Assistant	04/04/58	25
Newton, Isaac	BS, MS, PhD		Staff Scientist	05/05/53	50

Place this form at the end of the signed original copy of the application. Do not duplicate.

Social Security No. 123-45-6789

**PERSONAL DATA ON
PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR**

The Public Health Service has a continuing commitment to monitor the operation of its review and award processes to detect—and deal appropriately with—any instances of real or apparent inequities with respect to age, sex, race, or ethnicity of the proposed principal investigator/program director.

To provide the PHS with the information it needs for this important task, complete the form below and attach it to the signed original of the application after the Checklist. **Do not attach copies of this form to the duplicated copies of the application.**

Upon receipt of the application by the PHS, this form will be separated from the application. This form will **not** be duplicated, and it will **not** be a part of the review process. Data will be confidential, and will be maintained in Privacy Act record system 09-25-0036, "Grants: IMPAC (Grant/Contract Information)." All analyses conducted on the data will report aggregate statistical findings only and will not identify individuals.

If you decline to provide this information, it will in no way affect consideration of your application.

Your cooperation will be appreciated.

DATE OF BIRTH (MM/DD/YY)

03/03/38

GENDER

Female Male

RACE AND/OR ETHNIC ORIGIN (check one)

Note: The category that most closely reflects the individual's recognition in the community should be used when reporting mixed racial and/or ethnic origins.

- American Indian or Alaskan Native.** A person having origins in any of the original peoples of North America, and who maintains a cultural identification through tribal affiliation or community recognition
- Asian or Pacific Islander.** A person having origins in any of the original peoples of the Far East, Southeast Asia, the Indian subcontinent, or the Pacific Islands. This area includes, for example, China, India, Japan, Korea, the Philippine Islands, and Samoa.
- Black, not of Hispanic origin.** A person having origins in any of the black racial groups of Africa.
- Hispanic.** A person of Mexican, Puerto Rican, Cuban, Central or South American, or other Spanish culture or origin.
- White, not of Hispanic origin.** A person having origins in any of the original peoples of Europe, North Africa, or the Middle East.
- Check here if you do not wish to provide some or all of the above information

Inclusion Report Format For Each Study

Initially: Provide the number of subjects proposed for the study according to the following categories. If there is more than one study, provide a separate table for each study. In addition, report on the subpopulations that are proposed to be included in the study.

Annually: Provide the number of subjects enrolled in the study to date, according to the following categories. If there is more than one study, provide a separate table for each study. In addition, report on the subpopulations that are proposed to be included in the study.

Gender and Minority Inclusion

Study Title:

	American Indian or Alaskan Native	Asian or Pacific Islander	Black, not of Hispanic Origin	Hispanic	White, not of Hispanic Origin	Other or Unknown	Total
Female	50	50	50	50	50	100	350
Male	35	35	35	35	35	70	245
Unknown							
Total	85	85	85	85	85	170	595

Heading:

ST^194^123456789<NL>

BGN^00^UniversityGrantID01^19970602^1200^LT^^ // Date associated with signing official.
6C<NL> // Application is competitive renewal.

PWK^SD^DA^^^^^NIH File Upload<NL> // Research plan submitted as HTTP file upload

N9 Loop:

N9^4W^^TITLE<NL>

MTX^^ATHEROSCLEROSIS // Title of project.
PREVENTION STUDY<NL>

N9^CT^IR01AI0000001A1<NL> // Continuation of grant number...

N9^L4^J.I<NL> // Identify a beginning investigator

NM1 Loop:

NM1^1B^1^BRUNO^GIORDANO^^^JR<NL> // Name of the signing official.

N3^DEPT OF CONTRACTS & GRANTS^ // Address of the signing official.
1313 MOCKINGBIRD LANE<NL>

N4^BETHESDA^MD^20892<NL> // Address of the signing official.

N9^P5^^PROVOST & SENIOR VP FOR // Title of the signing official (SO).
ACADEMIC AFFAIRS<NL>

PER^IC^^TE^3015552396^FX^3015552835^EM^ // Telephone and FAX of the SO.
GIORDANO.BRUNO@UB.EDU^DEI-5555<NL> // Email and mail stop of SO.

NM1^AD^1^BRAHE^TYCHO^H<NL> // Name of administrative official (AO).

N3^DEPT OF CONTRACTS & GRANTS^ // Address of AO.
1313 MOCKINGBIRD LANE<NL>

N4^BETHESDA^MD^20892<NL> // Address of AO.

N9^P5^^DEPUTY DIRECTOR<NL> // Title of AO.

PER^IC^^TE^3015552396^FX^3015552835^EM^ // Telephone and FAX of AO
TBRAHE@MUNSTER.UB.EDU^DEI-5555<NL> // Email and mail stop of AO.

NM1^AZ^1^SCHMIDT^BERHARD<NL> // PI change. Name of former PI.

NM1^BY^2^^^^^1^927645168<NL> // DUNS number for NIH.

NM1^SE^2^UNIVERSITY OF BETHESDA^^^^^ // Applicant organization's name
1^112233445<NL> // Applicant's DUNS number.

N3^461 OCEAN BLVD.<NL> // Applicant's address

N4^BETHESDA^MD^20892<NL> // Applicant's city, state, and zip code

N9^CR^1234567<NL> // Applicant's number.

N9^EI^0123454321AI<NL> // Applicant's EIN.

Detail:

HL Loop:

HL^1^^PC^1<NL> // Project loop

DTM^193^19980401<NL> // Proposed period of support (From).

DTM^194^20000331<NL> // Proposed period of support (Through).

PAM^A3^24^MO<NL> // Planned duration of project.

NX1^A8<NL> // Type of organization.

N9 Loop:

N9^43^^MATRIX<NL> // Gender and minority inclusion matrix

MTX^^THIS IS WHERE THE GENDER AND // Study title.
MINORITY INCLUSION STUDY TITLE GOES. <NL>

INX Loop:

INX^1^1|A1|F2<NL> // Matrix start – absolute reference
// cells loaded horizontal, left to right.

K3^35<NL> // # of American Indian or Alaskan males

K3^35<NL> // # of Asian or Pacific Islander males

K3^35<NL> // # of Black males

K3^35<NL> // # of Hispanic males

K3^35<NL> // # of White males

K3^70<NL> // # of Other males

K3^50<NL> // # of American Indian or Alaskan females

K3^50<NL> // # of Asian or Pacific Islander females
 K3^50<NL> // # of Black females
 K3^50<NL> // # of Hispanic females
 K3^50<NL> // # of White females
 K3^100<NL> // # of Other females

N9^F4^M123456XB^PENDING<NL> // Assurance of compliance number.

N9^Y9^A9999-01^^
 19970201<NL> // Animal welfare assurance number.
 // IACUC approval date.

N9^L4^A<NL> // Abstract.

MTX^^THIS IS WHERE THE ABSTRACT WOULD GO<NL>

N9^L4^B.2<NL> // Research plan specific aims.

MTX^^THIS IS WHERE THE RESEARCH PLAN SPECIFIC AIMS WOULD GO<NL>

N9^L4^C.1<NL> // Budget justification.

MTX^^THIS IS WHERE THE BUDGET JUSTIFICATION WOULD GO<NL>

N9^L4^C.2<NL> // Space/Facilities

MTX^^*Laboratory: These studies will be performed in the laboratory of Dr. Galilei. Dr. Galilei's laboratory is located in the Clinical Research Center of the University of Bethesda. The laboratory contains sinks, benches, refrigerators, and freezers for in vitro studies.*

MTX^^*Clinical: There is full access to patients at the Pharmacology Research Laboratory in Bethesda, MD. In addition, there is support of community physicians.*

MTX^^*Animal: There are animal housing and procedure rooms in the Clinical Research Center. This facility is staffed by veterinarians and animal husbandry personnel.*

MTX^^*Computer: Dr. Galilei's laboratory contains a network of Pentium PCs with two color laser printers. The network has direct access to the Internet via the University of Bethesda backbone.*

MTX^^*Office: There are several offices adjacent to Dr. Galilei's laboratory with desks, bookshelves, filing cabinets and computer systems. These can be used by both investigators and administrative personnel.*

N9^L4^C.3<NL> // Equipment

MTX^^*The Clinical Research Center contains the following: Liquid scintillation counter, ultracentrifuge, refrigerated centrifuge, CO2 incubator, radioisotope detector, microscopes, balances, and a digital imaging system with computer control and perfusion equipment.*

N9^L4^E.4<NL> // Program income.

**MTX^^EXPECT TO RECEIVE \$50,000 FROM HOWARD HUGHES MEDICAL CENTER
DURING THE BUDGET PERIOD APRIL 1, 1998 THROUGH MARCH 31, 1999<NL>**

N9^L4^I.6<NL> // Inventions

MTX^^REPORTED<NL> // Invention was reported

PPL Loop:

PPL^^^T<NL> // Begin total project budget.

PD Loop:

PD^CC^19980401^DO^1^TPC^ // Project start date is Apr 1, 1998.
Total Project Cost^38<NL>

PDD^24^^1664082<NL> // Project is for 24 months; amount
// of funding requested is \$1,664,082.

PD^CC^19980401^DO^1^ANY^^84<NL> // Direct costs for total project budget.
// Use any value for PD05

PDD^24^^1098404<NL> // Total direct costs are \$1,098,404.

PD^CC^19980401^P1^51.50^ // Indirect rate for entire project period is 51.5%
ANY^^47<NL> // Use modified total direct cost base

PDD^24^1098404^ // Base amount for indirect costs
565678<NL> // Indirect costs for entire project period

PPL^^^I<NL> // Begin initial year project budget.

PD Loop:

PD^CY^19980401^DO||8S^110000^ANY^ // Institution base salary for person.
^01^GALILEI GALILEO^PRINCIPAL // Name and role of person.
INVESTIGATOR<NL>

PDD^12^4.8^44000^40<NL> // 12 months for initial budget.
// 40% of 12 months = 4.8 months.
// \$44000 is salary requested.
// 40% effort on project.

PD^CY^19980401^P1^31.3^ANY^49^ // 31.3 is % fringe benefits.
GALILEI GALILEO^PRINCIPAL // Fringe benefits for a person must
INVESTIGATOR<NL> // immediately follow the iteration of
// the PD loop identifying the person.

PDD^12^44000^13772<NL> // Dollar amount for fringe benefits.

PD^CY^19980401^DO|||8S^119719^ANY^^01^COPERNICUS NICHOLAUS^RESEARCH ASSISTANT<NL> // Copernicus' two entries are averaged

PDD^11^3.52^38574^32<NL> // 11 months for initial budget period
// (9 mon – academic, 2 mon – summer)
// Average % effort over 11 months is 32
// Combine requested salaries over 2 periods

PD^CY^19980401^P1^31.3^ANY^^49^COPERNICUS NICHOLAUS^RESEARCH ASSISTANT<NL>

PDD^9^11972^12073<NL> // Combine requested benefits over 2 periods.

PD^CY^19980401^DO|||8S^125000^ANY^^01^NEWTON ISAAC^STAFF SCIENTIST<NL> // Next budget entry for person.

PDD^12^1.2^0^10<NL> // No salary or fringe benefits are requested
// for this person.

PD^CY^19980401^DO|||8S^25331^ANY^^01^KEPLAR JOHANNES^SUPPORTEE<NL> // Next budget entry for person.
// This exemplifies a named, non-key
// person.

PDD^12^6^12666^50<NL>

PD^CY^19980401^P1^31.3^ANY^^49^KEPLAR JOHANNES^SUPPORTEE<NL>

PDD^12^12666^3964<NL>

PD^CY^19980401^DO|||8S^35000^ANY^^01^1^SUPPORTEE<NL> // Next budget entry for person.
// This exemplifies a non-key person,
// where the labor category is specified.

PDD^12^12^35000^100<NL>

PD^CY^19980401^P1^31.3^ANY^^49^1^SUPPORTEE<NL>

PDD^12^35000^10955<NL>

PD^CY^19980401^DO|||8S^32000^ANY^^01^1^LAB TECHNICIAN<NL> // Next budget entry for person.
// This exemplifies the budget for multiple
// non-key, non-named persons, where
// each person in a labor category
// (Technician) is specified on a
// separate line item.

PDD^12^12^32000^100<NL>

PD^CY^19980401^P1^30^ANY^^49^1^LAB TECHNICIAN<NL>

PDD^12^32000^9600<NL>

PD^CY^19980401^DO|||8S^36000^ANY^^01^1^LAB TECHNICIAN<NL>

PDD^12^12^36000^100<NL>

PD^CY^19980401^P1^30^ANY^^49^
1^LAB TECHNICIAN<NL>

PDD^12^36000^10800<NL>

PD^CC^19980401^DO^1^ANY^^70<NL> // Budget entry for total direct labor.

PDD^12^^198240<NL> // Sum of all salaries.

PD^CC^19980401^DO^1^ANY^^48<NL> // Budget entry for total fringe benefits.

PDD^12^^61164<NL> // Sum of all fringe benefits.

PD^CC^19980401^DO^1^ANY^^71<NL> // Budget entry for total salaries and benefits

PDD^12^^259404<NL> // Sum of all salaries and benefits.

PD^CC^19980401^DO^1^ANY^^81<NL> // Budget entry for consultant costs.

PDD^12^^22400<NL> // Cost for consultants.

PD^CC^19980401^DO^1^ANY^^42^^
**SINGLE CELL PERFUSION CHAMBERS
AND FILTER SETS**<NL> // Budget entry for equipment.

PDD^12^1^5500<NL> // Number and cost of equipment.

PD^CC^19980401^DO^1^ANY^^42^^
CENTRIFUGE<NL> // Next budget entry for equipment.

PDD^12^1^15000<NL> // Number and cost of equipment.

PD^CC^19980401^DO^1^ANY^^72<NL> // Budget entry for total equipment.

PDD^12^^20500<NL> // Sum of all equipment.

PD^CC^19980401^DO^1^ANY^^55<NL> // Budget entry for equipment maintenance.

PDD^12^^1183<NL> // Cost of equipment maintenance.

PD^CC^19980401^DO^1^ANY^^43<NL> // Budget entry for supplies.

PDD^12^^5400<NL> // Cost of supplies.

PD^CC^19980401^DO^1^ANY^^52^^
**TRAVEL TO NATIONAL MEETINGS FOR
3 INDIVIDUALS.**<NL> // Budget entry for travel.

PDD^12^^4000<NL> // Cost of travel.

PD^CC^19980401^DO^1^ANY^^80<NL> // Budget entry for publication costs.

PDD^12^^1500<NL>	// Publication costs.
PD^CC^19980401^DO^1^ANY^^85<NL>	// Budget entry for inpatient care costs.
PDD^12^^3500<NL>	// Cost of inpatient care.
PD^CC^19980401^DO^1^ANY^^BL<NL>	// Budget entry for outpatient care costs.
PDD^12^^84720<NL>	// Cost of outpatient care.
PD^CC^19980401^DO^1^ANY^^86<NL>	// Budget entry for animal costs.
PDD^12^^4400<NL>	// Animal costs.
PD^CC^19980401^DO^1^ANY^^87<NL>	// Budget entry for alterations/renovations.
PDD^12^^28750<NL>	// Cost of alterations and renovations.
PD^CC^19980401^DO^1^ANY^^39<NL>	// Budget entry for other expenses.
PDD^12^^35000<NL>	// Cost of other expenses.
PD^CC^19980401^DO^1^ANY^^03<NL>	// Budget entry for other direct costs.
PDD^12^^98633<NL>	// This is an aggregated amount.
PD^CC^19980401^DO^1^ANY^^84<NL>	// Budget entry for total direct costs
PDD^12^^470757<NL>	// This is an aggregated amount.
PD^CC^19980401^DO^1^ANY^^38<NL>	// Budget entry for total costs.
PDD^12^^713196<NL>	// This is an aggregated amount. Note // specification of length of initial budget // period.
PD^CC^19980401^P1^51.50^ANY^^47<NL>	// Indirect rate for initial budget period is 51.5% // Use modified total direct cost base
PDD^12^470757^ 242439<NL>	// Base amount for indirect costs // Indirect costs for initial budget period

PPL^^^2<NL>

// Begin second year project budget

PD Loop:

PD^CC^19990401^DO^1^ANY^^71<NL>	// Budget entry for total salaries and // benefits.
PDD^12^^465898<NL>	// Cost of salaries and benefits.

PD^CC^19990401^DO^1^ANY^^81<NL>	// Budget entry for consultant services.
PDD^12^^23296<NL>	// Cost of consultant services.
PD^CC^19990401^DO^1^ANY^^43<NL>	// Budget entry for supplies.
PDD^12^^5616<NL>	// Cost of supplies.
PD^CC^19990401^DO^1^ANY^^52<NL>	// Budget entry for travel.
PDD^12^^4098<NL>	// Cost of travel.
PD^CC^19990401^DO^1^ANY^^BL<NL>	// Budget entry for outpatient care costs.
PDD^12^^87648<NL>	// Cost of outpatient care.
PD^CC^19990401^DO^1^ANY^^39<NL>	// Budget entry for other expenses.
PDD^12^^41091<NL>	// Cost of other expenses.
PD^CC^19990401^DO^1^ANY^^03<NL>	// Budget entry for other direct costs.
PDD^12^^70003<NL>	// This is an aggregated amount.
PD^CC^19990401^DO^1^ANY^^84<NL>	// Budget entry for total direct costs.
PDD^12^^627647<NL>	// This is an aggregated amount.
PD^CC^19990401^DO^1^TC^^38<NL>	// Budget entry for total costs.
PDD^12^^627647<NL>	// This is an aggregated amount.

LX Loop:

LX^01<NL>	
NM1^61^2^ <i>PHARMACOLOGY RESEARCH LABORATORY</i> <NL>	// Performance site organization.
N4^ <i>BETHESDA</i> ^MD^20892	// Performance site city, state, and zip code.

LX^02<NL>	
NM1^K8^2<NL>	// Indicate DHHS indirect costs agreement

N9 Loop:

N9^AH^^CURRENT^19980101<NL>	// Date of DHHS agreement.
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HL Loop:

HL^2^1^26^1<NL> // Key person loop
QTY^E5^40<NL> // Level of effort for current budget period

LX Loop:

LX^1<NL>
NM1^9P^1^GALILEI^GALILEO^N<NL> // Identification of the PI
N2^UNIVERSITY OF BETHESDA<NL> // PI organization
N3^ATHEROSCLEROSIS RESEARCH UNIT^
461 OCEAN BLVD., CSC-32<NL> // PI address
N4^BETHESDA^MD^20892<NL> // PI city, state, and zip code
PER^IC^^ TE^3015551478^ // Telephone number of PI.
FX^3015552685^ // FAX number of PI.
EM^GGALILEI@UB.EDU^MSC-32<NL> // Email address and mail stop of PI.
DMG^^19380303^M^^7^1<NL> // DOB, sex, race, and citizenship of PI.

N9 Loop:

N9^19^^01^^^DP|MDK<NL> // Division and department of PI.
N9^P5^1^PROFESSOR OF MEDICINE<NL> // Position title of PI.
N9^SY^123456789<NL> // SSN of PI.
N9^L4^D.1<NL> // Experience of PI

MTX^^1963-1965: University of California, Los Angeles.
Department: Medicine. Resident.<NL>

N9^L4^D.1<NL>

MTX^^1965-1974: University of California, Los Angeles.
Department: Medicine. Medical Resident.<NL>

N9^L4^D.1<NL>

MTX^^1974-1979: University of California, Los Angeles.
Department: Medicine. Chief Resident.<NL>

N9^L4^D.1<NL>

MTX^^1979-1992: University of California, San Diego.
Department: Medicine. Associate Professor of Medicine.<NL>

N9^L4^D.1<NL>

MTX^^1992-1997: *University of Bethesda.*
Department: Medicine. Professor of Medicine.<NL>

N9^L4^D.3<NL> // PI honors.

MTX^^Years: *1994-1995 JM Osbourne Preventive Medicine Award*<NL>

N9^L4^D.3<NL>

MTX^^Years: *1995-1996 American Society for Immunology Travel Award*<NL>

N9^L4^D.4<NL> // PI memberships.

MTX^^Federal Advisory Committee Membership. Agency: NIDDK Title: GMA-2 Study Section
Start Year: 01/01/93 End Year: 01/01/1997<NL>

N9^L4^D.5<NL> // PI publications.

MTX^^Galilei, G., Brown C (1997). *The pathogenesis of coronary disease. New England Journal of Medicine, 236: 142-150.*<NL>

N9^L4^D.5<NL>

MTX^^Galilei, G., Robin, C. (1995). *Triggering of plaque disruption. Circulation, 81: 576-584.*<NL>

N9^L4^D.5<NL>

MTX^^Galilei, G., Dilbert D. (1995) *Arterial imaging and atherosclerosis reversal. Arterioscler Thromb. 14: 77-92.*<NL>

DEG Loop:

DEG^2.5^CM^195905^BS<NL> // Degree of PI.

FOS^M^^^MEDICINAL CHEMISTRY<NL> // Field of study for degree.

N1^1R^UNIVERSITY OF NORTHERN
ITALY<NL> // Educational institution.

DEG^4.4^CM^196312^MD<NL> // Degree of PI.

FOS^M^^^MEDICINE<NL> // Field of study for degree.

N1^1R^UNIVERSITY OF PISA<NL> // Educational institution.

HL Loop:

HL^3^2^OS^0<NL> // First other support project for Galileo

PAM^37^24^MO^F^186529^CC^ // Active support and annual direct costs
193^19960301^^194^19990228^^ // Support period start and end
14^30<NL> // Percent effort

LX Loop:

LX^1<NL>

NM1^92^2^NIH/NHLBI<NL> // Name of OS source

N9 Loop:

N9^CT^2R01HL00000013<NL> // OS project number

MTX^^Chloride and Sodium Transport in Airway // OS project title
Epithelial Cells<NL>

N9^K5^^GOALS<NL> // OS goals

MTX^^The major goals of this project are to define the biochemistry of chloride and sodium
transport in airway epithelial cells and clone the gene(s) involved in transport.<NL>

LX Loop:

LX^2<NL>

NM1^9P^1^GALILEI^GALILEO^N<NL> // Name of OS project PI

HL Loop:

HL^4^2^OS^0<NL> // Second other support project for Galileo

PAM^A3^24^MO^F^82163^CC^ // Pending support and annual direct costs
193^19981201^^194^20001130^^ // Support period start and end
14^20<NL> // Percent effort

LX Loop:

LX^1<NL>

NM1^92^2^NATIONAL SCIENCE // Name of OS source
FOUNDATION<NL>

N9 Loop:

N9^BD^DCB950000<NL> // OS project number

MTX^^*Liposome Membrane Composition and Function*<NL> // OS project title

N9^K5^^GOALS<NL> // OS goals

MTX^^*The major goals of this project are to define biochemical properties of liposome membrane components and maximize liposome uptake into cells.*<NL>

N9^YV^^OVERLAP<NL> // OS overlap

MTX^^*There is scientific overlap between aim 2 of NSF DCB 950000 and aim 4 of the application under consideration. If both are funded, the budgets will be adjusted appropriately in conjunction with agency staff.*<NL>

LX Loop:

LX^2<NL>

NM1^9P^1^GALILEI^GALILEO^N<NL> // Name of OS project PI

HL Loop:

HL^5^1^26^0<NL> // Key person loop

QTY^E5^25<NL> // Level of effort for current budget period

LX Loop:

LX^1<NL>

NM1^9K^1^COPERNICUS^NICHOLAS<NL> // Key person name

N2^UNIVERSITY OF BETHESDA<NL> // Key person organization

DMG^^19580404<NL> // Key person DOB.

EMS^RESEARCH ASSISTANT<NL> // Project role of key person.

N9 Loop:

N9^P5^1^CLINICAL INVESTIGATOR<NL> // Position title of key person.

N9^L4^D.1<NL> // Experience of key person.

MTX^^1983-1986: *National Institute of Allergy/Infectious Disease. Department: Lab of Clinical Investigation. Visiting Fellow.*<NL>

N9^L4^D.1<NL>

MTX^^1986-1992: *University of Bethesda.*

Department: Medicine. Medical Resident.<NL>

N9^L4^D.1<NL>

MTX^^1992-1997: *University of Bethesda.*
Department: Medicine. Clinical Investigator.<NL>

N9^L4^D.4<NL> // Key person memberships.

MTX^^Agency: *DRG NIH. Title: Ad hoc reviewer*
GMA-2 Study Section. Start year: 01/01/96<NL>

N9^L4^D.5<NL> // Key person publications.

MTX^^Copernicus, N., Pooh W. (1997) *Risk factor assessment and prevention of coronary artery disease. J Intern Med.;263:211-3.*<NL>

N9^L4^D.5<NL>

MTX^^Copernicus, N., McDonald R. (1997) *Cholesterol Lowering Atherosclerosis Study (CLAS). Controlled Clin Trials. 18:156-87.*<NL>

DEG Loop:

DEG^2.5^CM^197905^BS<NL> // Degree of key person.

FOS^M^^^^*BIOLOGICAL CHEMISTRY*<NL> // Field of study for degree.

N1^1R^UNIVERSITY OF CRACOW<NL> // Educational institution.

DEG^4.4^CM^198312^PHD<NL> // Degree of key person.

FOS^M^^^^*BIOLOGICAL CHEMISTRY*<NL> // Field of study for degree.

N1^1R^UNIVERSITY OF CRACOW<NL> // Educational institution.

HL Loop:

HL^6^1^26^1<NL> // Key person loop

QTY^E5^50<NL> // Level of effort for current budget period

LX Loop:

LX^1<NL>

NM1^9K^1^NEWTON^ISAAC<NL> // Key person name

N2^UNIVERSITY OF BETHESDA<NL> // Key person organization

DMG^^19530505<NL> // Key person DOB.

EMS^STAFF SCIENTIST<NL> // Project role of key person.

N9 Loop:

N9^P5^1^*BIOSTATISTICIAN*<NL> // Position title of key person.

N9^L4^D.1<NL> // Experience of key person.

MTX^^1982-1984: *Jackson Memorial Hospital,
Department: Medicine. Staff Research Associate.*<NL>

N9^L4^D.1<NL>

MTX^^1984-1988: *University of Illinois, Medical School.
Department: Medicine. Associate Specialist.*<NL>

N9^L4^D.1<NL>

MTX^^1988-1997: *University of Bethesda.
Department: Medicine. Associate Professor of Biometry.*<NL>

N9^L4^D.5<NL> // Key person publications.

MTX^^*Newton, I., Greenjeans, M. (1996) Effects of colestipol-niacin therapy on atherosclerosis.
Circulation. 38:138-47.*<NL>

DEG Loop:

DEG^2.5^CM^197505^BS<NL> // Degree of key person.

FOS^M^MATHEMATICS<NL> // Field of study for degree.

N1^1R^NEW UNIVERSITY COLLEGE,
LONDON<NL> // Educational institution.

DEG^4.25^CM^197806^MS<NL> // Degree of key person.

FOS^M^MATHEMATICS<NL> // Field of study for degree.

N1^1R^NEW UNIVERSITY COLLEGE,
LONDON<NL> // Educational institution.

DEG^4.4^CM^198212^PHD<NL> // Degree of key person.

FOS^M^BIOMETRY<NL> // Field of study for degree.

N1^1R^CAMBRIDGE UNIVERSITY<NL> // Educational institution.

HL Loop:

HL^7^6^OS^0<NL> // First other support project for Newton.
PAM^37^24^MO^F^581317^CC^ // Active support and annual direct costs
193^19970901^^194^20010831^^ // Support period start and end
14^70<NL> // Percent effort

LX Loop:

LX^1<NL>

NM1^92^2^*HOWARD HUGHES MEDICAL* // Name of OS source
CENTER<NL>

N9 Loop:

N9^CT^*INVESTIGATOR AWARD*<NL> // OS project number

MTX^^*Gene Cloning and Targeting for* // OS project title.
Neurological Disease Genes<NL>

N9^K5^^GOALS<NL> // OS goals

MTX^^*This award supports the PI's program to map and clone the gene(s) implicated in the*
development of Alzheimer's disease and to target expression of the cloned gene(s) to relevant
cells.<NL>

LX Loop:

LX^2<NL>

NM1^9P^1^*NEWTON^ISAAC^N*<NL> // Name of OS project PI

SE^288^123456789<NL> // Transaction set trailer.