OVERVIEW LABORATORY STUDIES

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OVERVIEW LABORATORY STUDIES

PLANNING AND CONDUCTING LABORATORY STUDIES

1. PURPOSE This Guide provides an overview of the process of planning and conducting laboratory studies in the Center for Food Safety and Applied Nutrition (CFSAN).

2. REFERENCES Details associated with the specifics of planning and conducting laboratory studies are contained throughout this manual. Other references are:

   A. Center for Food Safety and Applied Nutrition, Tactical Plan: Instructions for developing the Tactical Plan.

   B. Center for Food Safety and Applied Nutrition, Resources Reporting System Via Profs (RSVP): RSVP Workbook.

   C. Preparation of the current year's Tactical Plan: Instructions for Developing the Tactical Plan issued annually by CFSAN Planning Branch, DPFM (HFS-666).

   D. Good Laboratory Practice Regulations: 21 CFR Part 58.

3. POLICY All laboratory work conducted in the Center must be planned and conducted in accordance with the policies and procedures established by this manual.

4. PROCEDURES The procedures identified below sequentially define the steps required for planning and conducting non-clinical laboratory (GLP) studies and other Center research. All studies are planned on a fiscal year basis and planning begins a year in advance. Unplanned research that emerge outside of the scheduled planning sequence can take place at any time provided that the same review and approval process identified below is followed. Neither nonclinical laboratory studies nor any other research will be initiated without the approval of the Research and Nonclinical Laboratory Study Selection Committee (See CFSAN/QA Laboratory Manual Guide 3002.13). Nonclinical laboratory studies are

subject to the GLP Regulations, if there are any questions as to which studies fall within the purview of the GLP Regulations, consult with the Quality Assurance Staff.

A. Planning Process

1. Planning Branch will issue guidelines to Center Strategic Managers on developing their program strategies, goals and objectives for the following fiscal year. Guidelines are to be issued third week of October.

2. Center management shall solicit ideas for proposed studies from center scientist. These ideas would then be forwarded to the appropriate representative of the Research and Nonclinical Laboratory Study Selection Committee for consideration during the third week of October. (See CFSAN/QA Laboratory Manual Guide 3002.13).

3. The Research and Nonclinical Laboratory Study Selection Committee shall identify the compounds of regulatory interest and establish the direction that research is to take in the Center for the following fiscal year. This Committee will meet in mid-November to develop a list of proposed research, in priority order, based on the needs and interest of the Center. The Committee shall distribute the list of research needs to the strategic managers and Office Directors within one week of the mid-November meeting.

4. Office Directors, Division Directors and/or Branch Chiefs make research assignments to scientific personnel based on recommendations from the Research and Nonclinical Laboratory Study Selection Committee. Research assignments are made according to Center priority and the availability of resources. Line management shall assure that there is coordination of research efforts without unnecessary duplication. Research assignments are made to prospective study directors/principal investigators by February 1, with instructions to prepare tactical plan.

5. Study directors/principal investigators, as directed by their Office and Division Managers shall prepare the Tactical Plan project descriptions according to the instructions distributed by the

Planning Branch, DPFM. Project descriptions shall contain a project abstract, a statement of mission relevance, a description of activities as well as information regarding staffing and special equipment needs, milestones and outside collaborators. Each Tactical Plan shall be reviewed and approved by line management prior to being submitted to the strategic Manager for Research. The Tactical Plan development process begins in mid April.

6. Tactical Plans that have been signed by the study unit line management are submitted to the Strategic Manager for Research for review and approval by the appropriate Strategic Manager for the specific research area.

7. At the time the Tactical Plan is approved by the Strategic Manager, the Study Director/Principal Investigator shall obtain commitments for study support from appropriate sources (See CFSAN/QA Laboratory Manual Guides 3002.17 and 3002.18).

B. Contract Priorities

1. Research needs that are determined to be conducted by contract are identified in the Tactical Plan prepared by the project manager and submitted to the Strategic Manager for review. The approved Tactical Plan is then submitted to the Extramural Review Committee for consideration of funding.

2. The Extramural Committee shall meet to establish contract priorities based on the research needs of the Center and available resources (see CFSAN/QA Guide 3003.03 for Contracting Research). The Committee shall meet in mid July to determine which of the proposed contracts will be approved for funding.

C. Protocol Preparation, Review and Approval

1. Study Director (GLP studies)/principal investigators (other research) shall prepare protocols for studies identified in approved Tactical Plans. All protocols shall be developed using the CFSAN Study Protocol form (FDA form 3244) or by using the computer version of the form in Word Perfect 5.1 (See CFSAN/QA Guide 3009.03, Study Protocol).

Both the form and the computer disk are available from the QAS. Protocols are submitted to line management for review and approval.

2. The Division Director must conduct a scientific review of each protocol to assure that the methods and procedures proposed are adequate to fulfill the experimental objective. The Division Director is also responsible for assuring that the research conducted in his/her specific unit is relevant to the Center's needs.

3. Protocols for studies involving the use of animals shall be reviewed by the Institutional Animal Care and Use Committee (IACUC) to determine if animals utilized in Center research are humanely treated with minimization of pain and discomfort (See CFSAN /QA Laboratory Manual Guide 3002.15, Institutional Animal Care and Use Committee).

4. All Protocols are reviewed by the Quality Assurance Staff to determine if they are subject to the Good Laboratory Practice regulations. Those protocols that are determined from the review to be non-GLP and conform to the Center's quality assurance standards will be signed and dated by the QAS and assigned a BFQ number. The protocol (original) is returned to the principal investigator to begin his/her research. Protocols are to be retained with the study records. Protocols that are determined to be subject to the GLP will be reviewed for compliance with the regulations (21 CFR, Part 58) by the QAS and comments, if any, will be forwarded to the Study Director for correction.

5. The Study Director shall review the comments make necessary corrections and submit the revised protocol to the QAS for approval and the assignment of to BFQ number. The QAS will return the approved (official) protocol to the Study Director.

D. Conducting Research

1. The Study Director/Principal Investigator shall assure that procedures indicated in the approved protocol are followed by study personnel and that appropriate documentation is maintained to support the results of the research conducted.

2. Line management (study unit) must review the progress of research conducted in their area of responsibility on a periodic basis.

E. Study Modifications

1. Significant changes to Tactical Plan projects must be made by the Project Manager (study director/ principal investigator) using a Resource Reallocation form. The Resource Reallocation form and the instructions regarding its use may be obtained from the Planning Branch, DPFM. Completed forms are to be submitted to the Planning Branch, HFS-666.

2. Changes in the approved protocol must be amended promptly by the Study Director (GLP study)/Principal Investigator (other research) using the CFSAN - Protocol Amendment form (FDA 3244a) or the computerized Version of the Protocol Amendment (Word Perfect 5.1). Both the form and the disk are available from the QAS. Protocol Amendments must be submitted to the QAS as quickly as possible.

3. Amendments to the protocol that involve changes or addition to animal procedures must be approved by the chairperson of the IACUC prior to being submitted to the QAS.

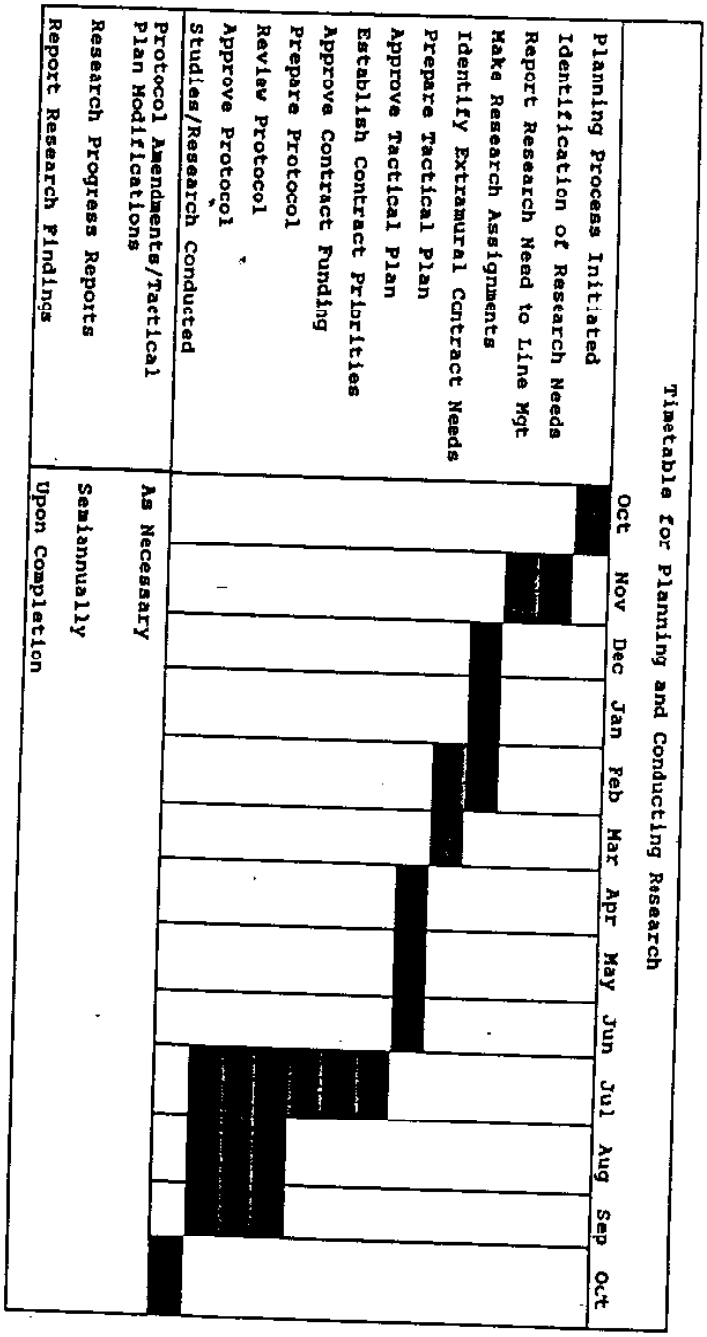
F. Reporting Process

1. Project Managers (study director/principal investigator) shall prepare semiannual progress reports which outline achievements made toward accomplishing milestones cited in the Tactical Plan. The progress reports are submitted to the appropriate Strategic Manager through study unit line management.

2. At the completion of a GLP study, the Study Director is required to prepare a final report according to 21 CFR, Part 58 (See CFSAN/QA Guide 3009.05, Nonclinical Laboratory Study - Final Report). Once the final report has been audited and approved by the QAS manuscripts may be prepared and presentations may be given (See CFSAN/QA Guide 3009.02, publications and Presentations).

3. At the conclusion of other research (non-GLP) the principal investigator is required to prepare a written report that includes the results and conclusions of the research conducted. This document is to be reviewed by line management, signed and dated indicating supervisory approval of the reports content.

4. Investigators are to prepare manuscripts and presentations of research findings (See CFSAN/QA Guide 3009.02, Publications and Presentations).


Timetable for Planning and Conducting Research
Oct
Nov
Dec
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Planning Process Initiated
Identification of Research Needs
Report Research Need to Line Mgt
Make Research Assignments
Identify Extramural Contract Needs
Prepare Tactical Plan
Approve Tactical Plan
Establish Contract Priorities
Approve Contract Funding
Prepare Protocol
Review Protocol
Approve Protocol
Studies/Research Conducted
Protocol Amendments/Tactical Plan Modifications
As Necessary
Research Progress Reports
Semiannually
Report Research Findings
Upon Completion

OVERVIEW LABORATORY STUDIES

MONITORING LABORATORY STUDIES

1. PURPOSE This Guide establishes CFSAN-wide procedures for the monitoring of all laboratory studies to ensure that the research is conducted in accordance with sound quality assurance practices and procedures.

2. POLICY All laboratory research conducted either by/or for the Center shall be monitored by the Quality Assurance Staff (QAS) to assure management that the conduct of the research is in conformance with either the Good Laboratory Practice Regulations or Center Quality Assurance Principles.

3. PROCEDURES

   A. Laboratory studies conducted within the Center for Food Safety and Applied Nutrition.

      1. Nonclinical Laboratory Studies

         A. Line Management shall assure that the studies carried out within their units are being conducted in accordance with the GLP Regulations.

         B. The Quality Assurance Staff shall be responsible for monitoring each nonclinical laboratory study to assure management that the facilities, equipment, personnel, methods, practices, records and controls are in conformance with the GLP Regulations.

The QAS shall inspect each phase of a non-clinical laboratory study periodically to assure the integrity of the study. The Quality Assurance Staff shall maintain a master schedule which shall contain the current non-clinical studies, critical phase inspection dates, final report data audit and approval dates. Any significant problems which are likely to affect study integrity found during the course of an inspection shall be brought to the attention of the study director and management immediately. Management has five days to respond to the reported deviations. The response shall indicate the corrective action that has or will be taken to confirm that the deviations have been corrected. The most frequent GLP violations found upon QAS inspection are given in Attachment A.

C. Food and Drug Administration investigators (Office of Regional Operations) will periodically inspect Center Laboratories for compliance with the Good Laboratory Practice Regulations. The Commissioner has made a policy decision that these inspections be performed even though not specifically required by the regulation.

The investigators are authorized to inspect the facilities, records and specimens as well as photocopy any record necessary from GLP studies identified on the master schedule maintained by the Quality Assurance Staff. Study deviation reports generated by and on file with the CFSAN Quality Assurance Staff are not subject to review by the FDA investigators. See Attachment B for the procedures to follow during an ORO inspection.

2. Other Research

A. Branch Chiefs are responsible for internal inspections to assure that the quality of research conducted within their particular branch is in conformance with the approved Division Plan. Inspections and corrective action plans shall be documented and retained as evidence of monitoring.

B. The Center Quality Assurance Staff shall also monitor other research for adherence to Division QA Plans. This monitoring shall be conducted at least once a year with follow-up inspection as necessary to review any corrective actions. The Quality Assurance Staff shall use, as the basis for the monitoring the Division QA checklist. (See Chapter 5, Employee Management, CFSAN/QA Laboratory Manual Guide 3005.04, Division Laboratory Quality Assurance Plans.)

B. Contract Studies

Laboratory studies conducted under contract for the Center for Food Safety and Applied Nutrition must conform to the same quality assurance standards as those conducted within the Center. (See CFSAN/QA Guide 3003.03, Contracting Laboratory Studies).

OAS INSPECTION OF NONCLINICAL LABORATORY STUDIES MOST FREQUENT VIOLATIONS

1. Documents and raw data are not signed and dated.
2. Corrections are not initialed or dated.
3. Transcribing mistakes.
4. Protocols are not amended and authorized when changes are made.
5. SOP's are not revised.
6. Use of pencil for data entries.
7. Erasures or white out used.
8. Duplicates are not corrected like the originals.
9. SOP's are not followed.
10. Calibration records are not maintained.
11. Unapproved protocols are in the possession of study personnel.

CFSAN PROCEDURES DURING ORO GLP INSPECTIONS

Reception and Identification

1. The receptionist will receive the investigators upon their arrival and call the Director of the Center. If the Director is unavailable, one of the Deputy Directors or the person in change of the Center at the time will be called.

2. The receptionist will call a representative from the CFSAN Quality Assurance Staff.

3. The entrance interview will be held in the Office of the Director or the Office of the Deputy Director.

4. The investigators will be asked for their official identification and a notice of inspection upon their arrival. Only the Director and Deputy Directors of the CFSAN my receive the notice of inspection unless they designate another person as the responsible individual.

5. The inspectors will be given a designated room to use during the time they are inspecting the laboratories.

Inspection Procedures

1. During the tour of the laboratory, the investigators will be accompanied by a member of the Quality Assurance Staff.

2. Investigators are not permitted to enter animal rooms within the barrier (MOD I) or other areas unless they wear proper protective clothing and safety glasses in compliance with the appropriate SOP.

3. Investigators should be accompanied by a QAS representative at all times (except in their designated room).

4. Investigators may request appropriate data generated for a particular study (i.e. if they are auditing and/or inspecting a subchronic study on test article A, they may request protocols, raw data, specimens, interim and final reports for this study only). All raw data and specimens must be returned to the QAS representative or study director at the end of each day.

5. The QAS representative will notify the appropriate supervisor and study director that the inspection is in progress.

6. Quality assurance reports and records other than audit logs and the master schedule will not be available to the investigators.

7. All raw data and specimens are to be examined on the premises under the supervision of the QAS representative.

8. The investigators will report to the QAS representative at the start of each day.

9. During the inspection the QAS representative should record questions and answers that are discussed between the investigator and CFSAN personnel.

Exit Interview

1. The exit interview will be attended by the Director of the Center or a designated member of this staff, a QAS Representative, appropriate study director(s) and their supervisors and other individuals that management would request to be in attendance.

2. All deviations addressed by the investigators should be answered verbally during this interview and confirmed in writing within ten (10) days of the exit interview.

OVERVIEW LABORATORY STUDIES

EXTRAMURAL PROJECTS ASSOCIATED WITH NON-CLINICAL LABORATORY STUDIES

1. PURPOSE The purpose of this guide is to describe the procedures and policies within the Center for Food Safety and Applied Nutrition (CFSAN) for the preparation and clearance of the Memorandum of Need (MON) for extramural projects associated with nonclinical laboratory studies.

2. POLICY The procedures in this guide shall be used when preparing MONs for extramural projects used to obtain nonclinical laboratory studies.

3. DEFINITIONS The following definitions are for terms associated and/or used when preparing MONs. Other definitions associated with activities and responsibilities in the FDA Office of Contracts and Grants Management (OCGM) can be found under the various Reference documents.

   A. Contracts

      The legal, binding, mutually agreed-upon document between the Food and Drug Administration and another party to perform specific requirements.

   B. Cooperative Agreements

      A financial assistance mechanism to be used in lieu of a grant when substantial Federal programmatic involvement with the recipient during performance is anticipated.

C. Cooperative and Research Development Agreements (CRADAs)

An agreement between one or more Federal laboratories and one or more non-Federal parties under which the Government, through its laboratories, provides personnel, services, facilities, equipment, or other resources with or without reimbursement (but not funds to non-Federal parties) and the non-Federal parties provides funds, personnel, services, facilities, equipment, or other resources toward the conduct of specified research or development efforts which are consistent with the missions of the laboratory.

D. Extramural Projects

Extramural Projects are outside formal activities with private and/or international entities or other government agencies which conduct studies, investigations, surveys, tests, or analyses of a scientific, technical or medical nature. The activities can be in the form of a contract, grant (including cooperative agreements), or interagency agreement (IAG). Extramural Projects are funded under either the extramural or appropriate operational allotment.

E. Grants

A financial assistance mechanism whereby funds and/or direct assistance is provided to carry out approved activities. A grant (as opposed to a cooperative agreement) is to be used whenever the FDA awarding office anticipates no substantial programmatic involvement with the recipient during performance of the financially assisted activities.

F. Interagency Agreement (IAG)

Any formal agreement between FDA and another Federal agency which involves FDA providing or receiving a transfer of funds, provision of services, loan of staff, use of property, facilities or equipment, or exchange of information.

G. Memorandum of Need (MON)

Document initiated by CFSAN program staff and sets forth the requirements for contracts and IAGs.

H. Memorandum of Understanding (MOU)

A formal agreement between FDA and another government agency (Federal, State, or local) or an information agreement with foreign governments or other foreign institutions. A MOU may not be used when involving personnel, or a transfer of personnel, transfer of funds, or real property.

I. Mini-Memorandum of Need (Mini-MON)

Document which reflects only the changes that are needed to an original contract or IAG. e.g. Change in period of performance and/or funding amount and accounting data for a new fiscal year.

J. NonClinical Laboratory Studies

Any in vivo or in vitro experiment in which (1) a test article is studied prospectively in a test system under laboratory conditions to determine its safety; (2) the test article is an FDA-regulated product; (3) the data from the study may be used in a regulatory decision or may be cited in a court case; and (4) the test system is any animal, plant, microorganism, or subparts thereof to which the test or control article is administered or added for study.

K. Project Officer

The CFSAN employee who is technically responsible for writing the MON, monitoring, coordinating and evaluating the work done under a contract, IAG, or grant. Must satisfactorily complete the DHHS Basic Project Officers course.

L Project Advisory Group (PAG)

A group of three or more persons who serve as an advisory and review body on technical matters during the contracting process. Members of the PAG must have a Procurement Integrity Certification on file with OCGM.

M. Service Projects

Service Projects are activities which can also be in the form of a contract or interagency agreement but are mainly related to administrative and support type services. Service Projects are funded under specific operational allotments and are being included in the extramural review.

N. Small Purchases

Procurements for supplies and services and the total cost is under $25,000.

4. REFERENCES

A. FDA Project Officer Guide Series Volume I - Guidelines for Obtaining Special Contract Clearances/Approvals. Volume II - Statements of Work (SOW's).

B. OCGM Interagency Agreement Internal Operations and Procedures Manual June 29, 1990

C. FDA Staff Manual Guide - FDA 2113.1 "FDA Scientific Review and Development Projects". **(DATE)**

D. FDA Staff Manual Guide - FDA 2610.1 "Acquisitions of Medical or Scientific Requirements and Supporting Services Under Negotiated Contracts" **(DATE)**

E. FDA Staff Manual Guide - 2810.1 "Interagency Agreements" **(DATE)**

F. Nonclinical Laboratory Studies - Good Laboratory Practices (Federal Register)

G. FDA Organization for Operation of the Federal Technology Transfer Act (FTTA) of 1986

5. PROCEDURES:

Extramural Reviews

Each year, a call goes out for the submission of a Contract Description Form (Attachment A) for each extramural project (contracts, IAGs, grants, and cooperative agreements). After ensuring that the form has all the necessary approvals, the Office Directors priorities the various projects and forward them to the Extramural Resource Staff.

The Extramural Resource Staff puts together the CFSAN Fiscal Year Extramural Project Plan. Copies of the Fiscal Year Extramural Project Plan are distributed to the Extramural Review Committee (ERC) (Center Director, Deputy Directors and Strategic Managers) and the Office Directors.

Depending on the availability of the Center Director and Deputy Directors, Extramural Review Meetings are scheduled for 2-3 hours over a 2-3 day period. An invitation is also extended to the Contracting Officer, Contracts Operations Branch, OCGM.

Office Directors give oral presentations on the various projects and then the floor is open for questions, discussions and/or comments on the projects. The ERC makes recommendations on each of the projects and proposed level of funding.

The Extramural Staff prepares and distributes a final report on the outcome of the ERCs. The Projects Officers are notified as to when the MON for their approved project should be submitted to the Extramural Staff.

G. RESPONSIBILITIES

A. Extramural Staff

The Extramural Staff, Financial Management Office, Division of Planning and Financial Management, Office of Management Systems, is responsible for all aspects included in the coordination and administration of contracts, grants, cooperative agreements, IAGs, CRADAs, and procurements. Within their responsibilities, they ensure that MON packages are complete, funds are available to support the project, get the appropriate CFSAN approvals, and forward the package to the appropriate staff in OCGM. A complete MON package contains the MON, approved funding certification (HHS-393) (Attachment B), Independent Government Cost Estimate (IGCE) (Attachment C), Special Program Clearance and Approval Checklist (Attachment D) and completely signed Signature Page (Attachment E).

B. Project Officer

Project Officers will be responsible for coordinating MON activities with the Extramural Staff and preparing the MON and Mini-MONs. Complete MON Packages are forwarded to the Extramural Staff. The project officer schedules and presides at meetings of the PAG to review proposals, and as needed, meets with Contracting Officers staff and participates in the negotiations. After award of a contract or grant, and/or the execution of an IAG, the project officer is responsible for monitoring the various activities and work through its completion.

C. Quality Assurance Staff

The Quality Assurance Staff will be responsible for the review of any planned extramural project that falls within the definition of a nonclinical laboratory study. The review will ascertain if the planned project(s) is in accordance with the Good Laboratory Practice Regulations (GLP). A representative of the Quality Assurance Staff will be available to serve on the Project Advisory Group for all projects involving nonclinical laboratory studies.

Contract Number:

Fiscal Year 1995 Contract Description Form

1. Contract Title:

2. Program (✓ one):	3. Period of Performance:	4. Contract Status (✓ One):
☐ 1. Chemical Safety of Foods ☐ 2. Microbiological Safety of Foods ☐ 3. Nutrient Quality & Food Labeling ☐ 4. Cosmetics Safety & Labeling ☐ 5. Infrastructure & Crosscutting Activities	Start Date: End Date:	Renewal ☐ New ☐
5. Project Officer's Name:	6. Mail Code:	7. Tel. Number:

8. Estimated Costs		
FY 1994:	FY 1995:	FY 1996:

9. Project Description (Objectives, Mission Relevance, Description of Work):

Approval

Branch Chief:	Date:
Division Director:	Date:
Office Director:	Date:
Other (SMs or Collaborating Centers):	Date:
Strategic Manager for Research (if appropriate):	Date:

September 21, 1994

DEPARTMENT OF
HEALTH AND HUMAN SERVICES
PURCHASE/SERVICE/STOCK REQUISITION

BPA and Call No. _____

REQUISITION NUMBER
B 00654
OFFICE CODE/SYMBOL

TO

REQUEST FOR
☐ PURCHASE ☐ SERVICE ☐ STOCK ISSUE ☐ RENTAL/LEASE

REQUESTING ORGANIZATION

CUSTODIAL AREA | DATE | OBJECT CLASS

FOR REFERENCE CALL

EXTENSION

APPROPRIATION

DELIVER TO

CAN

DATE REQUIRED

ITEM NO.	DESCRIPTION (INCLUDE STOCK NUMBER, MODEL/PART NO., ETC.)	QUANTITY REQUIRED	UNIT OF ISSUE	COST UNIT	COST TOTAL

I certify that the property/services requested are required for Government business, and are not available from excess or current assets.*

FUNDS AVAILABLE (Signature/Title) | DATE | TOTAL

REQUESTED BY (Signature/Title)* | DATE

RECOMMEND APPROVAL (Signature/Title)* | DATE

APPROVED BY (Signature/Title)* | DATE

PROPERTY MANAGEMENT OFFICER (Signature)* | DATE

RECEIVING OFFICIAL - I certify that the quantities indicated in the "Quantity Required" column above have been received in total or as annotated.

RECEIVING OFFICIAL (Signature/Title) | DATE

ORDER NO. (PO, DO, FEDSTRIP, ETC.) | ORDER DATE

VOUCHER NO. | VOUCHER DATE

HHS-393 (Rev. 6/80)

INDEPENDENT GOVERNMENT COST ESTIMATE WORKSHEET

(In accordance with FDA 2610.4)

MON.

COST ELEMENT	NO. OF MAN-HRS.	HOURLY WAGE	ESTIMATED TOTAL	COST ELEMENT TOTAL
1. LABOR CATEGORIES/TITLES				
a.			$	
b.				
c.				
d.				
e.				
f.				
g.				
h.				
			SUBTOTAL	$
2. EQUIPMENT – Itemized	QUANTITY	UNIT COST		
a.				
b.				
c.				
d.				
			SUBTOTAL	$
3. TRAVEL – Itemize specific trips				
PER DIEM (_____ Days X $_____ Per Day)			$	$
4. MATERIALS AND SUPPLIES (Itemize by such categories as Food, glassware, office supplies, etc.) a. Publication/Reproduction				
b. Communication/telephone				
c.				
d.				
e.				
f.				
g.				
h.				
i.				
j.				
			SUBTOTAL	$
			SUBTOTAL THIS PAGE	$

FORM FD 3052a (7/77)

Continued on Reverse

				COST ELEMENT TOTAL
			FORWARDED FROM SIDE 1	$
COST ELEMENT	QNTY	UNIT COST	ESTIMATED TOTAL	
6. CONSULTANT FEE(S) (No consultants ____ X No. Days ____ X $ ____ Per Day)				$
6. OTHER DIRECT COST a. Publication/Reproduction			$	
b. Communication/Telephone			$	
c.			$	
			SUBTOTAL	$
7. SUBCONTRACTS (Itemize cost on separate sheet and identify by MON No)				$
8. OTHER COST ITEMS NOT INCLUDED ABOVE a.			$	
b.			$	
c.			$	
			SUBTOTAL	$
			DIRECT COSTS SUBTOTAL OF ITEMS 1 THROUGH 8	$
9. OVERHEAD (____ % of TDEC of $ ____)				$
10. GENERAL ADMINISTRATIVE EXPENSE (G and A at ____ % x $ ____)				$
			DIRECT AND INDIRECT COST TOTAL	$
11. FEE/PROFIT (____ % of total through item 10)				$
			TOTAL ESTIMATED COST	$
CONTRACT SPECIALIST (Type or print name)	SIGNATURE			DATE
PROJECT OFFICER (Type or print name)	SIGNATURE			DATE
COMMENTS				

Special Program Clearances & Approval Checklist

Introduction: The following checklist must be attached to each Memorandum of Need submitted to the Contracting Officer. The applicability of these clearances is discussed in the Project Officers Guide Series Volume 1. The Project Officer must indicate which of the clearances apply, if any.

MON No. _____

Applicable	Not Applicable	SECTION A - SPECIAL CLEARANCES/APPROVALS REQUIRED PRIOR TO APPROVAL OF THE MON
_____	_____	1. DATA PROCESSING SYSTEMS APPROVAL
_____	_____	2. COMMERCIAL OR INDUSTRIAL PRODUCTS OR SERVICES CLEARANCE (A CONTRACT vs. IN-HOUSE PERFORMANCE REVIEW AND DETERMINATION PURSUANT TO OMB CIRCULAR A-76)
_____	_____	3. PAID ADVERTISING APPROVAL
_____	_____	4. PRINTING SERVICES CLEARANCE
_____	_____	5. APPROVAL OF STUDIES ON FRAUD, ABUSE, AND WASTE IN FDA PROGRAMS
_____	_____	6. SURVEY, RECORDKEEPING AND REPORTING BURDENS CLEARANCE
_____	_____	7. SAFETY AND HEALTH APPROVAL FOR CONTRACTS INVOLVING HAZARDOUS SUBSTANCES
_____	_____	8. APPROVAL OF CONTRACTS WITH PRESENT OR FORMER FEDERAL EMPLOYEES
_____	_____	9. CLASSIFIED CONTRACTS CLEARANCE
_____	_____	10. PUBLICATIONS APPROVAL
_____	_____	11. AUDIOVISUAL (VIDEOTAPE, TELEVISION AND MOTION PICTURE) PRODUCTION APPROVAL
_____	_____	12. PRIVACY ACT (P.L. 93-579) SYSTEMS OF RECORDS DETERMINATION
_____	_____	13. APPROVAL FOR PROVIDING GOVERNMENT PROPERTY
_____	_____	14. ENVIRONMENTAL IMPACT DETERMINATION
_____	_____	15. ADVISORY COMMITTEE APPROVAL
_____	_____	16. MICROGRAPHICS APPROVAL
_____	_____	17. APPROVAL OF CONTRACTS WITH STATE GOVERNMENTS
_____	_____	18. TRAINING CONTRACTS CLEARANCE
_____	_____	19. CLEARANCE FOR RELEASE OF PRIVILEGED INFORMATION TO CONTRACTORS
_____	_____	20. GOOD LABORATORY PRACTICES
_____	_____	21. CONSULTANT SERVICES

		SECTION B - CLEARANCES/APPROVALS REQUIRED PRIOR TO CONTRACT AWARD
_____	_____	1. APPROVAL FOR PROJECTS INVOLVING HUMAN SUBJECTS
_____	_____	2. ANIMAL WELFARE APPROVAL
_____	_____	3. FOREIGN RESEARCH CONTRACT CLEARANCE
_____	_____	4. EEO (OVER $1,000,000)

The above indicated clearances apply to this procurement and the appropriate clearance documents are attached or action has been initiated to obtain them.

_____
CONTRACT COORDINATOR

_____
PROJECT OFFICER

SIGNATURE PAGE

Project Title:

Identification Number:

Funding Data: See Attached HHS-393
(Requisition Number _____)

_____
Project Officer

APPROVED:

_____ _____
Director, Division_**(APPROPRIATE)**_ Date

_____ _____
Director, Office -**(APPROPRIATE)**- Date

_____ _____
Acting Financial Management Officer Date

_____ _____
Director, Division of Planning and Financial Management Date

_____ _____
Director, Office of Management Systems Date

_____ _____
Director, Center for Food Safety and Applied Nutrition Date

_____ _____
Director, Office of Financial Management Date