CHAPTER 20

STAFFING NEEDS FOR RESEARCH DIET STUDIES

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STUDY DESIGN AND INTENSITY OF EFFORT

The work of the nutrition research kitchen is time-consuming and labor-intensive, and requires a high degree of precision and meticulous attention to detail. The nutrition research team thus needs to be highly motivated and well trained to ensure that protocols are executed correctly. The size of the team and the number of staff with particular skills are best determined by evaluating the study's ''design elements'' — that is, the operational features that distinguish one protocol from another. Because the activities required for research diet studies are so different from those of typical institutional foodservice, the time and personnel estimates in this chapter are based on the authors' own experience.

The following aspects of study design (''design elements'') should be assessed when planners consider each study's staffing requirements:

- **Is the study conducted on an inpatient (resident) or outpatient (nonresident) basis?** Inpatient studies generally require staff coverage for 2 or 3 shifts, 7 days per week. Outpatient studies, however, can be surprisingly labor intensive because considerable effort is needed to coordinate participants' schedules, package the foods for take-out, accommodate food pickup times, monitor quality assurance procedures, and address compliance issues. On the other hand, outpatient studies tend to enroll larger numbers of participants and may realize economies of scale, particularly in procurement of food and other supplies.
- **Which nutrients are to be controlled?** The amount of time to design the diet increases when more nutrients are designated for control. In addition, certain nutrients are more difficult to manipulate, which means that the research kitchen will be engaged in more complex production techniques.
- **Are nutrition screening or dietary intake assessments part of the protocol?** Compared to height and weight, the more complex anthropometric measurements such as skinfold thickness or lean body mass take more time. If dietary intake data are to be collected, the frequency and method should be determined. Any need for counseling or intervention also will directly alter the demand for professional staff time.
- **What data collection instruments will be used?** Some studies require the research dietitian to design specific instruments. This can be time-consuming as the instrument is developed, tested, and refined.
- **What is the ''size'' of the study?** To estimate each study's staff requirements, it is necessary to determine the total length of the study, the number of diet periods, and the total number of participants enrolled at any time. Some studies may have high staffing needs for short periods of time; others have low staffing needs for longer periods of time. Protocols that require simultaneous multiple diets will be more labor intensive.
- **How complex is the diet protocol?** The precision of the study diet determines the staff time required. Consideration should be given to: the diet protocol specified (ie, metabolic balance, constant, controlled nutrient, weighed, estimated, or liquid formula); the length and number of diet study periods; the menu design (ie, 1-day fixed menu, cycle menu, or self-selected menu); recipe development and standardization; quality assurance procedures; and the number of diet composites required for nutrient analysis.

Information about the study's design elements and other features of the research plan, derived from answers to these questions, can be used to rank protocols by intensity of effort. (See Tables 20-1, 20-2, and 20-3.) Time and labor es-

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ABLE 20-1

esign Elements Classification Guide for Outpatient (Nonresident) Studies[1]

Design Element	Low Effort	Medium Effort	High Effort
Number of subjects	<10	10–30	>30
Length of study	Days to weeks	Weeks—4 months	>4 months
Diet complexity	Standard house or therapeutic diets with routine cafeteria or tray service	One nutrient altered or restricted	Multiple nutrients altered or restricted
	One dietary treatment produced and served	Two concurrent dietary treatments produced and served	Three or more concurrent dietary treatments produced and served
	Foods not weighed	Limited number of test foods weighed	All food items weighed to meet caloric needs of individual subjects
	No need to produce specialized test foods	One specialized food produced to deliver test nutrients	Multiple specialized foods produced to deliver test nutrients
	No meals eaten off-site	Some meals packed for off-site consumption	Many meals packed for off-site consumption
Menu cycle length	1 day	2–7 days	>7 days
Diet composites	Limited number of high-priority foods are composited	One day's menu from each treatment is composited in duplicate for analysis before the study begins	Individual days' menus and/or complete menu cycles for each treatment are composited before the study and throughout each diet period
Number of dietary staff	<5	5–10	>10
Nutrient intake questionnaires (Qx)	Single Qx with long-turnaround data analysis	Multiple Qx with medium-turnaround data analysis, or single Qx with short-turnaround data analysis	Multiple Qx with short-turnaround data analysis
Method for assessing energy requirements	Predictive equations (eg, Harris-Benedict)	Calorimetry by doubly-labeled water method	Multiple food records analyzed by computer
Body composition measurements	Single assessment	Single assessment	Multiple assessments
	Anthropometric measurements (eg, height, weight, skinfold thickness)	Laboratory measurements (eg, bioelectrical impedance, hydrostatic weighing, DEXA)[2]	Anthropometric and laboratory measurements
Biological samples	1–2 blood samples	Multiple blood samples	Multiple collections of blood, urine, feces, etc
		24-hr urine collections	Any invasive procedure

[1]This classification guide was developed by Beverly Clevidence, PhD, at the Beltsville Human Nutrition Research Center, US Department of Agriculture, Beltsville, Md.
[2]DEXA, dual-energy X-ray absorptiometry.

Source: "Well-Controlled Diet Studies in Humans, A Practical Guide to Design and Management", American Dietetic Association, © 1999.

TABLE 20-2

otocol Intensity Ranking Guide[1]

Protocol Features	Low Intensity	Medium Intensity	High Intensity
Diet design	Special diet for simple, one-component study; not individualized	Special diet for individual subjects	Any protocol with ''medium'' ranking and additional component
Setting	Inpatient or outpatient	Inpatient or outpatient	Inpatient or outpatient
Meal production	Regular meals or snacks only Standard therapeutic meals (eg, low-fat, diabetic)	Special diets with one restriction	Special diets with multiple restrictions Weighed diets with computer analysis
Anthropometric measurements	One-time bioelectrical impedance tests or skinfold thickness measurements	Sequential bioelectrical impedance or skinfold thickness measurements Hydrostatic weighing with residual volume measurement Calorimetry	Combined body composition measurements (eg, hydrostatic weighing, skinfold thickness)
Nutrient data services	Single nutrient intake questionnaire with simple data analysis Subject-kept food diaries Long turnaround time for data analysis	Multiple nutrient intake questionnaires with simple data analysis Calorie counts with analysis by food exchange groups Medium turnaround time for data analysis	Multiple nutrient intake questionnaires with complex data analysis Calorie counts with computer analysis Short turnaround time for data analysis
Other		Activities include analysis and reporting of data	Activities include study and protocol design, writing grant applications, hiring and supervising staff, writing data publications Dietitian(s) must be certified for data collection and testing

[1]This ranking guide was adapted from a model originally developed by the late Donna Nickel, MS, RD, at the behest of the Dietitians' Administrative Committee (Karen Todd, MS, RD, chairperson), General Clinical Research Center Program, National Center for Research Resources, Bethesda, Md.

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TABLE 20-3

Examples of Intensity-Ranked Protocols[1]

Protocol Features	Low-Intensity Protocol: "Serotonergic Mediation of Dimethyl Tryptamine Effects in Humans"	High-Intensity Protocol: "Trial of Ca^{2+} Supplementation in Pregnancy for the Prevention of Preeclampsia and Preterm Birth"
Number of subjects	24	900
Setting	Inpatient (IP)	Outpatient (OP)
Subject days or visits	4 IP days/ subject (2 IP days/ visit x 2 visits/subject)	4 OP visits/ subject
Meal production	Regular meals (some vegetarian) One meal per subject	No meals provided
Nutrient data services	None	Nutrition research manager hires/supervises 0.5 FTE dietitian(s) for study. Dietitian(s) certified annually to obtain two 24-hour recalls per subject.
Clinical services	None	Referral to hospital obstetrics/gynecology department if necessary

[1]These examples were adapted from a set originally developed by the late Donna Nickel, MS, RD, at the behest of the Dietitian's Administrative Committee (Karen Todd, MS, RD, chairperson), General Clinical Research Center Program, National Center for Research Resources, Bethesda, Md.

timates can then be adjusted up or down accordingly. Ranking studies in this manner is especially useful when staff are synchronizing the effort for multiple simultaneous protocols. (The guidelines provided throughout this chapter are generally geared toward medium-intensity protocols.)

The Personnel Organization of Controlled Diet Studies

The organizational structure of the nutrition research unit should ensure that the core functions of a controlled feeding protocol can be achieved. These functions include: scientific management; institutional management and financial support; ethical, scientific, and financial oversight; recruitment and management of participants; preparation and delivery of the dietary intervention; laboratory analysis; and data management and analysis.

There are many ways of assigning the responsibilities needed to achieve these functions (see Exhibit 20-1). Similarly, a wide variety of institutions, with widely varying internal organizational structures, can provide appropriate settings. Among these are private research foundations, university laboratories, and industry laboratories. The organizational structure needed to conduct a single study, such as one that may be supported by a single research grant, is relatively simple (see Figure 20-1).

If multiple concurrent studies are undertaken, more delegation of responsibility is needed, with a more hierarchical approach and, perhaps, more narrowly defined position descriptions and job titles (see Figure 20-2). The National Institutes of Health General Clinical Research Centers (GCRCs) have a unique organizational structure that is mandated by the funding agency (see Figure 20-3).

Under ideal circumstances, the professional nutrition staff and the principal investigators for specific studies will develop strong collegial relationships that are personally rewarding and scientifically productive, with respectful acknowledgment of areas of responsibility and expertise. In most settings, doctoral-level principal investigators have overall responsibility for the study, playing the key role of initiating the research program and obtaining funds. The principal investigator develops the study's main scientific hypotheses, lays out the basics of the research plan, oversees data analysis and interpretation, and arranges for review of human subjects protection. (The oversight roles of the principal investigators and medical officers are addressed in Chapter 5, "Ethical Considerations in Dietary Studies.") The principal investigator and the nutrition research manager together must ensure that the study's hypotheses are reflected in the dietary design and that the research kitchen and the biochemical laboratory have a smoothly coordinated working relationship.

Nutrition Personnel

By considering the particular skills and responsibilities of the personnel who are employed in the nutrition research kitchen, it generally is possible to make a distinction between the managerial and the staff categories. The principal functions, responsibilities, and guidelines for several dif-

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EXHIBIT 20-1

Responsibilities of Study Personnel[1]

Research Coordinator/Study Coordinator
Manages clinical feeding study. Works closely with principal investigator and biostatistician to develop research and recruitment strategies and to establish study schedule. Manages data flow between laboratory and biostatistician. Works directly with research dietitian, subject coordinator, and biomedical coordinator to elicit compliance with study goals and objectives. May be responsible for ordering and purchasing supplies.

Subject Coordinator
Works closely with study participants during recruitment and screening. Promotes retention and compliance throughout the study. Acts as a liaison among study participants and research management staff. (These responsibilities can also be assigned to the research coordinator when appropriate.)

Biomedical Coordinator
Coordinates and schedules biological sample collection. Manages laboratory personnel and data collection and analysis.

Medical Technician
Draws blood samples and collects other biological samples from study participants. Must be appropriately qualified according to rules of sponsoring institution.

Biochemical Laboratory Technician
Performs chemical and other assays on biological samples according to study protocol.

Biostatistician
Works closely with principal investigator to develop optimal study design to achieve research objectives and to determine the most powerful data analysis approach. Conducts statistical analysis of study data.

Data Management Assistant
Assists biostatistician with data management activities (coding, data input, programming, data analysis).

Research Dietitian/Administrative Dietitian/Senior Research Dietetic Technician
Develops study diet according to research objectives. Works directly with food production technicians to monitor quality of food products. Trains and manages food production technicians and food service assistants. May share responsibilities for purchasing food and supplies.

Food Production Technician/Dietetic Technician/Nutrition Technician/Nutrition Research Manager
Prepares and portions special foods and meals according to the study protocol.

Foodservice Assistant/Food Production Assistant
Assists in preparing and portioning meals and other aspects of food service for study participants.

[1]Job titles and assigned responsibilities will vary among research centers. The role of the principal investigator is discussed under The Personnel Organization of Controlled Diet Studies. General Clinical Research Centers follow personnel guidelines provided by the funding agency.

ferent positions are listed in Exhibit 20-1 (exact job titles may vary among institutions). There also may be need for a study coordinator, a recruiter, and a quality assurance specialist.

Nutrition Research Manager

The principal function of the nutrition research manager is to manage the administrative, research, and clinical responsibilities of a nutrition research unit. (A typical position description is shown in Exhibit 20-2.) Responsibilities include protocol design and implementation; management of the research kitchen; and participant nutritional care (Table 20-4). Many GCRC units have only one research dietitian, who also functions as the nutrition research manager. The diversity of the unit's activities, the number of protocols, and the required nutrition services will all have the potential to influence professional staffing needs. Functional time analyses are often required to justify additional professional staff

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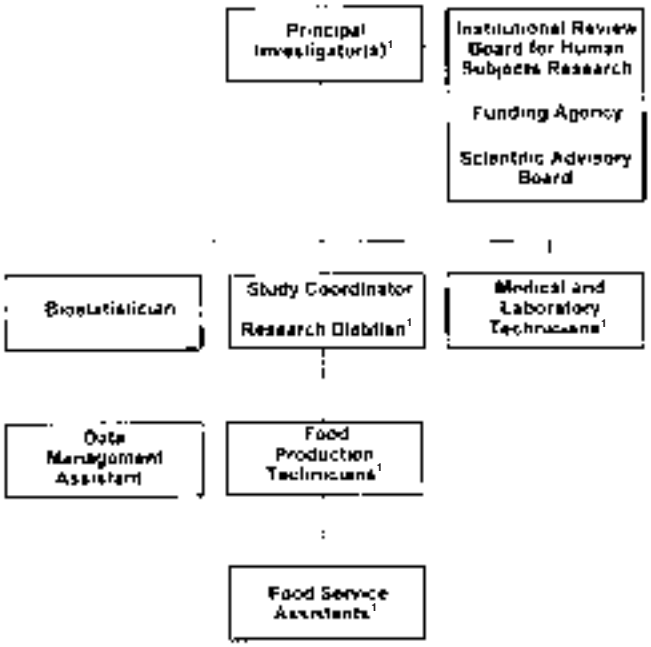

FIGURE 20-1. Organizational structure: single feeding studies.

[1]Has contact with study participants.

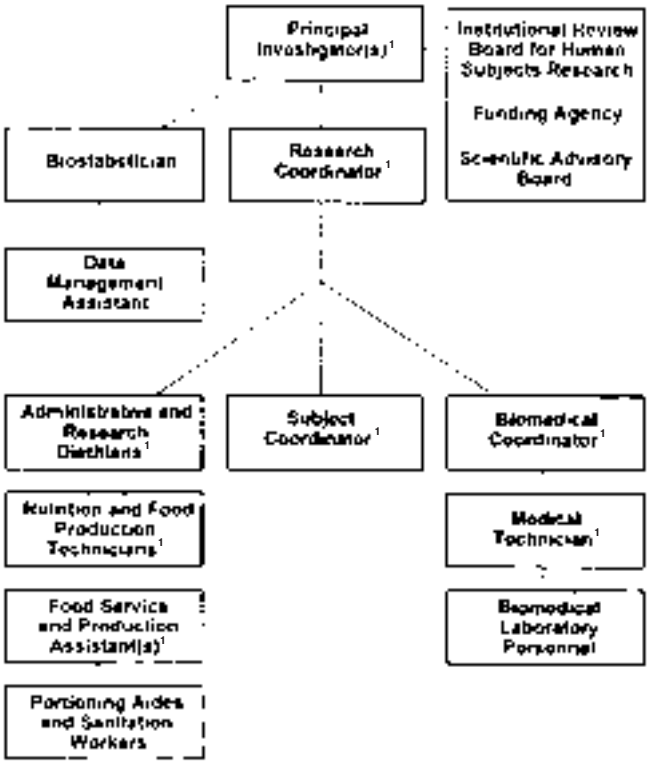

FIGURE 20-2. Organizational structure: multiple concurrent feeding studies

[1]Has contact with study participants.

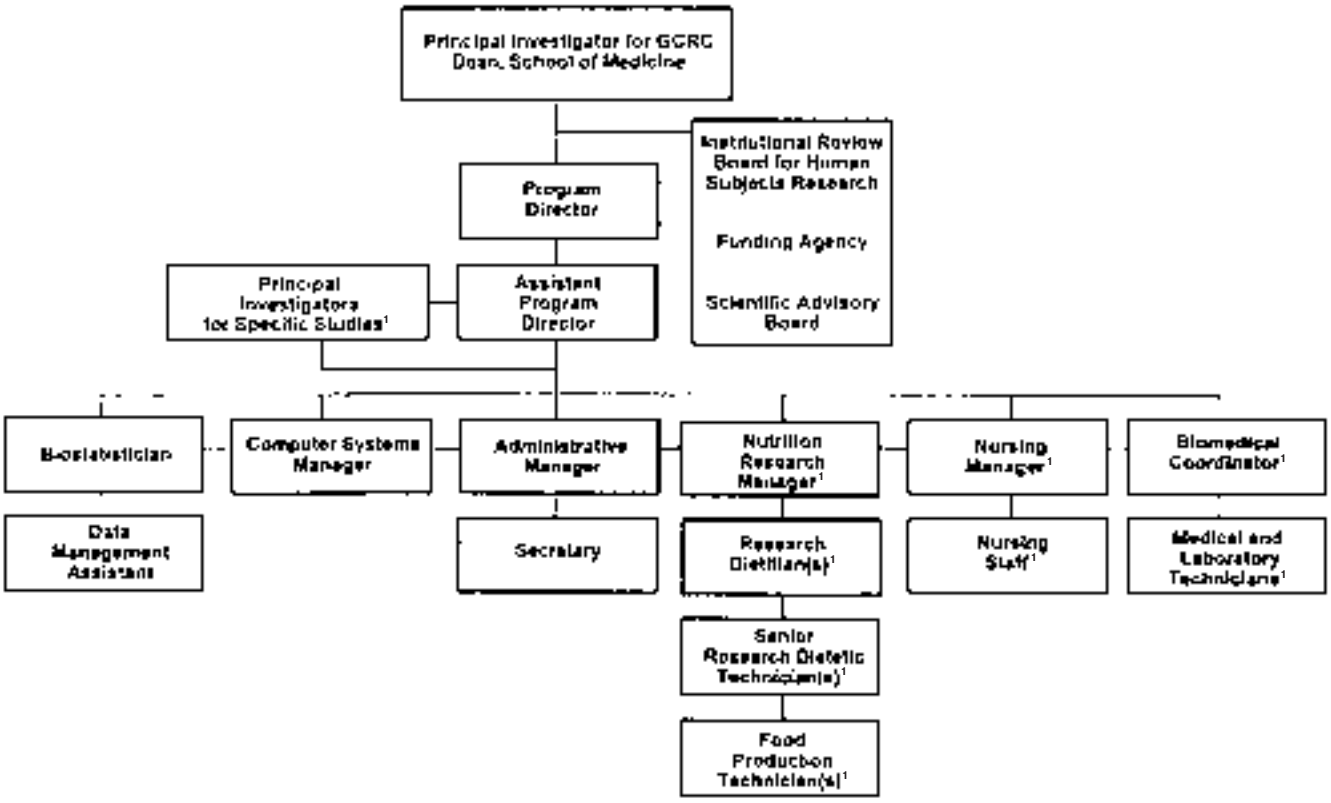

FIGURE 20-3. Organizational structure: General Clinical Research Center.

[1]Has contact with study participants.

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EXHIBIT 20-2

Position Description: Nutrition Research Manager

PRINCIPAL FUNCTION

Manages the administrative, research, and clinical nutrition responsibilities of a nutrition research unit. Responsible for designing and implementing dietary protocols, managing the research kitchen, and providing nutritional care to study participants.

DUTIES AND RESPONSIBILITIES

Administrative

- Manages the operation of the research kitchen to ensure accurate delivery of diets as defined by research protocols.
- Develops all policies and procedures for the nutrition research unit.
- Recruits, hires, trains, supervises, and evaluates nutrition research personnel.
- Prepares annual budget for personnel, equipment, and supplies.
- Maintains standards for sanitation, safety, and quality assurance.
- Prepares reports of activities of the nutrition research unit for annual reports, site visits, and grant applications and renewals.
- Serves on the clinical research center advisory committee and evaluates the nutrition aspects of research protocols.
- Evaluates, uses, and maintains computer systems to manage food purchasing and preparation and to analyze food consumption data.
- Consults with architects and kitchen design consultants to plan for remodeling and/or expansion of the nutrition research facility as needed.

Research and Clinical

- Collaborates with clinical investigators to plan, organize, conduct, and evaluate the nutrition component of research protocols.
- Designs and implements research diets consistent with the scientific purpose of each project, general nutrition principles, and the needs of individual research participants.
- Performs nutritional assessments, makes recommendations regarding nutritional care, and records data in the medical record.
- Collects and interprets nutrition-related data; participates in the publication and presentation of research findings to the scientific community and the lay public.
- May develop and conduct independent nutrition research projects.
- Informs research participants of the dietary aspects of research protocols, and evaluates compliance.
- Develops individualized nutrition education materials for research projects and provides nutrition counseling.
- Attends conferences and educational symposiums to maintain current knowledge in clinical nutrition, food science, and research methodology.
- Trains clinical investigators, graduate students, dietetic interns, and support personnel in nutrition research design and methodology.
- Establishes and maintains positive interdisciplinary professional relationships to facilitate planning and implementation of research projects and effective participant nutrition care.

QUALIFICATIONS

Education

- Masters or doctoral degree in nutrition or related field.
- Undergraduate concentration in clinical dietetics preferred.

Job Knowledge and Skills

- Must possess thorough knowledge of theory and practices of dietetics and nutritional sciences.

Experience and Training

- Completion of an approved dietetics education program and registration by The American Dietetic Association.
- Three years of clinical experience.
- Exposure to clinical research preferred.
- Managerial or supervisory experience highly desirable.

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TABLE 20-4

Task Descriptions: Nutrition Research Manager

Task	Activities
Protocol design	Review scientific literature. Hold conferences/teleconferences with investigators and other research dietitians. Develop data collection instruments and/or nutrition education materials.
Research diet design	Calculate nutrient composition by computer analysis. Verify nutrient content by chemical analysis. Develop and standardize recipes.
Subject interviews	Screen subjects. Collect data to calculate energy needs. Review research diet, protocol, and compliance issues. Schedule meal pickup times for outpatient studies.
Data collection	Obtain diet history and 24-hour recall. Provide instructions for food records and other questionnaires. Clarify data recorded.
Individualized diet calculations	Adapt designed research diets for individual subjects as needed (primarily for energy level).
Nutritional care	Assess nutritional status of subjects. Plan, implement, and monitor care for subjects. Conduct nutritional counseling, document medical records, and refer for discharge.
Communications	Hold conferences with investigators, other research dietitians, nurses, and subjects. Annotate charts in the medical record.
Employee training	Hire, recruit, and train employees to: prepare food in accordance with research methodology; prepare diet composites for chemical analysis; interview subjects and instruct them in compliance procedures; and enter food intake data using nutrition software.
Employee supervision	Provide ongoing training and supervision specific to varied protocols. Counsel and implement disciplinary action.
Quality assurance	Establish and maintain an integrated quality assurance program.
Computer resources	Manage periodic improvements of nutrient databases and software.
Data preparation	Prepare dietary intake data for analysis.
Publications and presentations	Participate in data analysis and writing groups with other investigators. Prepare scientific manuscripts for publication. Present data and other study information at professional meetings.

(Table 20-5). Because the production and delivery of research diets are so costly and labor-intensive, it is critical that estimates of time requirements and staff needs be available when the overall research budget is being developed and when funding applications are being written.

Nutrition Research Staff

The principal function of the senior research dietetic technician is the management of the nutrition research kitchen. This includes supervision of staff, production and service of research diets, inventory and purchase of food and supplies, and quality assurance. Some units may employ an administrative dietitian with the management responsibilities of both the senior research dietetic technician and the nutrition research manager. Position tasks and functional time analysis estimates for nutrition research staff are found in Tables 20-6 and 20-7. (Position descriptions are shown in Exhibits 20-3 and 20-4.)

Other Staff

The exact job titles and position descriptions can vary considerably for the staff who prepare and portion foods, deliver food to study participants, and handle many of the logistical aspects of the research kitchen and dining room. Some responsibilities for data collection also may be included. These staff members may have the job titles of cooks, chefs, food-service assistants, food production technicians, nutrition technicians, portioning aides, and sanitation workers.

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ABLE 20-5

unctional Time Analysis Estimates for Different Types of Research Diets: Nutrition Research Manager[1]

sk	Formula Diet	Weighed Diet	Constant Diet	All Diets
otocol design	1–3 hr/protocol	5 hr/protocol	10 hr/protocol	—
esearch diet design	10 hr/diet	20 hr/diet	40 hr/diet	—
ubject interviews	0.50–0.75 hr/subject	0.50–0.75 hr/subject	0.50–0.75 hr/subject	—
patient (IP)				
utpatient (OP)	—	—	—	Add 25% to IP diet estimates
ata collection				
thropometric measurements	—	—	—	0.25–0.5 hr/subject
etary assessment and history	—	—	—	0.5 hr/subject
ood record instruction	—	—	—	0.5 hr/subject
Clarification	—	—	—	0.17 hr/day of recorded intake
Food frequency questionnaires	—	—	—	0.5–1 hr/subject
Individualized diet calculations				
IP protocols	0.17 hr/menu[2]	0.17 hr/menu[2]	0.17 hr/menu[2]	—
OP protocols	—	—	—	Add 25% to IP diet estimates
Nutritional care	—	—	—	2 hr/subject
Communications	0.25 hr/subject/wk	0.50 hr/subject/wk	0.25 hr/subject/wk	—
Employee training				
Research methods	—	—	—	20 hr/staff member; 1 hr/protocol
Entry of dietary intake data	—	—	—	40 hr/staff member; 1 hr/protocol
Compliance	—	—	—	1 hr/staff member; 0.25 hr/protocol
Quality assurance	—	—	—	1 hr/protocol
Employee supervision				
Orientation	0.25 hr/protocol	0.5 hr/protocol	0.5 hr/protocol	—
Menu design	0.5 hr/protocol	0.5 hr/protocol	1 hr/protocol	—
Recipe standardization	0.5 hr/protocol	2 hr/protocol	2 hr/protocol	—
Subject instruction	0.25 hr/protocol	0.5 hr/protocol	0.5 hr/protocol	—
Quality assurance	1 hr/protocol	10 hr/protocol	20 hr/protocol	—
Computer resources	1 hr/protocol	2 hr/protocol	2 hr/protocol	Add 2 hr/month for all diets
Diet preparation	0.5 hr/subject	1 hr/subject	1 hr/subject	—
Publications and presentations	—	—	—	[3]

[1]The various types of research diets are described in Chapter 10, ''Planning Diet Studies.''
[2]0.17 hr = 10 min.
[3]See the Conclusion and Exhibit 20-9 of this chapter for further discussion of publications and presentations.

Source: "Well-Controlled Diet Studies in Humans, A Practical Guide to Design and Management", American Dietetic Association, © 1999.

TABLE 20-6

Task Descriptions: Nutrition Research Staff

Task	Activities
Protocol development	Assess personnel needs. Determine freezer and refrigeration capacity for storage. Prepare written procedures for nutrition protocols.
Recipe testing and standardization	Assist in menu development. Develop, test, and standardize recipes. Determine product shelf-life. Prepare standardized forms for quality assurance using computer software.
Nutritional care	Instruct research subjects in procedures necessary for compliance with research studies. Monitor and record food intake. Write menus. Obtain food preferences. Perform anthropometric measurements.
Dietary assessment	Enter food intake data using nutrition software. Assist in analyzing nutrient content of research diets and recipes. Assist in other calculations as necessary.
Quality assurance	Assist in the development of data collection forms. Tabulate and prepare data for analysis. Record and monitor food intake and compliance. Record and monitor weight to ensure weight stabilization. Prepare diet composites for chemical analysis.
Communications	Maintain telephone, interpersonal, and written communication among participants, research dietitians, nutrition research staff, nurses, and investigators.
Employee training	Train employees in procedures required for nutrition protocols, including food preparation techniques, sanitation and food safety, use of computer software, food record and menu analysis.
Employee supervision	Schedule and direct the activities of the nutrition research staff. Maintain continuous quality assurance checks on procedures for weighing food items, methods for preparing foods, and records for data collection.
Ordering and inventory	Order food items and maintain inventory of food and supplies.
Preparing and portioning food	Weigh, measure, and prepare food portions and ingredients using standardized methods. Wrap, label, and store food items using standardized procedures.
Sanitation	Clean work areas and equipment using established procedures.
Food safety	Portion food for cooling and storing into appropriate containers. Label and date food items. Monitor refrigerator and freezer temperatures.
Outpatient study activities	Coordinate meal pickup times with subjects' schedules. Pack and label meals using established procedures.

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TABLE 20-7

Functional Time Analysis Estimates for Different Types of Research Diets: Nutrition Research Staff[1]

Task	Formula Diet	Weighed Diet	Constant Diet	All Diets
Protocol development	1 hr/protocol	2 hr/protocol	5 hr/protocol	—
Recipe testing and standardization	2–3 hr/protocol	5–10 hr/protocol	60 hr/protocol	—
Nutritional care	0.25 hr/subject	0.5 hr/subject	1 hr/subject/wk	—
Dietary assessment	—	—	—	0.33–0.50 hr/recorded day
Quality assurance				
Develop protocols	0.25 hr/protocol	0.50–1 hr/protocol	20 hr/protocol	—
Monitor compliance	0.25 hr/protocol	0.50–1 hr/subject	1 hr/subject/wk	—
Prepare diet composites	1 hr/composite	4–8 hr/composite	4–8 hr/composite	—
Communications	0.25 hr/subject/day	0.25 hr/subject/day	0.25 hr/subject/day	—
Employee training	0.50 hr/protocol	1 hr/protocol	8 hr/protocol	—
Employee supervision	0.50 hr/protocol	0.50 hr/protocol	2 hr/day	—
Ordering and inventory	—	—	—	6–8 hr/week
Preparing and portioning food	0.5 hr/formula	0.25 hr/meal	0.75 hr/meal	—
Sanitation	—	—	—	0.50–1 hr/day
Food safety	—	—	—	0.25–0.50 hr/day
Outpatient study activities	—	—	—	Add 0.33 hr/subject/day

[1]The various types of research diets are described in Chapter 10, ''Planning Diet Studies.''

A typical position of this type is that of the food production technician (sometimes termed research dietetic technician). The principal function of the food production technician is the preparation and service of meals to research subjects on controlled nutrient diets in accordance with established methods and procedures. This staff member also assists with the collection and entry of dietary intake data using computer software. (For a position description see Exhibit 20-5.)

Planning Considerations

To determine staffing needs, it is important to identify the tasks to be performed (''task descriptions'') and to estimate the time required for each (''functional time analysis estimates''). Task descriptions for the nutrition research manager and the nutrition research staff are shown in Tables 20-4 and 20-6. Functional time analysis estimates for various aspects of nutrition protocols, particularly for three commonly used types of research diets, are shown in Tables 20-5 and 20-7. These are provided as examples of time requirements and can be altered to fit specific situations. Because each research center will develop its own unique experience of the time and effort required to carry out various activities, planning activities for new protocols can benefit greatly from information gained during recently completed projects.

There are several ways to estimate total research kitchen staff effort for a controlled diet protocol. Small studies and inpatient studies often must allot 1 to 2 full-time employees (FTE) for each 3 to 4 participants who are receiving weighed, constant, controlled nutrient, or metabolic balance diets. It may be necessary to distribute the effort among several individuals to ensure that all work shifts are covered and there are no gaps when a staff member is on leave. Some large-scale studies ($n > 25$), which serve half of the meals on site with the other half packed for off-site consumption, allocate 1 FTE per 5 to 6 participants.

Staffing needs also are affected by the number and complexity of concurrent studies and the total number of participants engaged in all studies. Large studies may require staffing patterns that vary greatly through the course of the week. Some nutrition research units have found that using an evening shift can yield an increase in production without requiring a concomitant increase in kitchen space and equipment.

Another approach is to conduct a task analysis to determine the estimated production time per meal. This exercise is shown for a sample protocol (''Protocol 809: Adipose Tissue Distribution and Adrenergic Mechanisms in Aging''). The first step is to describe the key features of the protocol (see Exhibit 20-6). Next, the study's design elements and methods are summarized (see Table 20-8). Information from this summary, in conjunction with worksheets that link specific professional tasks to required effort, can be used to

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EXHIBIT 20-3

Position Description: Senior Research Dietetic Technician

PRINCIPAL FUNCTION

Responsible for management of the nutrition research kitchen. This includes supervision of staff, production and service of research diets, inventory and purchase of food and supplies, and quality assurance.

DUTIES AND RESPONSIBILITIES

Administrative

- Ensures accuracy and precision in the preparation of controlled diets for research protocols.
- Plans, directs, and supervises the activities of nutrition research staff.
- Trains employees in appropriate methods and techniques of food preparation for the implementation of nutrition protocols.
- Participates in the performance evaluation of nutrition research staff.
- Inventories and orders food and supplies.
- Supervises and assists in the production and delivery of research meals.
- Assists in the development of recipes and menus to meet research protocol specifications.
- Maintains food safety and sanitation standards; monitors quality assurance.
- Updates policy and procedure manuals.
- Supervises the cleaning and maintenance of equipment in work area.
- Maintains communication among subjects, research dietitian, and nutrition research staff.
- Uses computer software for food purchasing and inventory control.

Research and Clinical

- Instructs research subjects in the dietary procedures necessary for compliance with research studies.
- Monitors and records food intake; reinforces compliance with research protocols.
- May write diets, obtain participant food preferences, take anthropometric measurements, and participate in the nutrition education of participants.
- May clarify dietary intake records; gather and prepare data for analysis.

QUALIFICATIONS

Education

- Graduate of an approved dietetic technician program (or equivalent education and experience).

Job Knowledge and Skills

- Must be able to manage the foodservice operation of a nutrition research kitchen.
- Must have knowledge of basic food preparation, nutrition, and food composition.
- Must have good interpersonal skills.

Experience and Training

- One year related work experience.
- Computer literacy desirable.

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EXHIBIT 20-4

Position Description: Administrative Dietitian (or Nutrition Research Manager)

PRINCIPAL FUNCTION

Responsible for management of the nutrition research facility. This includes supervision of staff, production and service of research diets, inventory and purchase of food and supplies, and quality assurance.

DUTIES AND RESPONSIBILITIES

Administrative

- Manages the operation of the research kitchen to ensure accurate delivery of diets as defined by research protocols.
- Develops and updates all policies and procedures for the nutrition research service.
- Maintains policy and procedure manuals.
- Recruits, hires, trains, supervises, and evaluates nutrition research personnel.
- Prepares annual budget for personnel, equipment, and supplies.
- Maintains food safety and sanitation standards; monitors quality assurance.
- Ensures accuracy and precision in the preparation of controlled diets for research protocols.
- Inventories and orders food and supplies.
- Assists in the development of recipes and menus to meet research protocol specifications.
- Supervises the cleaning and maintenance of equipment in work areas.
- Maintains communication among subjects, research dietitian, and nutrition research staff.
- Maintains computer systems to manage food purchasing and inventory control.
- Consults with architects and kitchen design consultants to plan for remodeling and/or expansion of the nutrition research facility as needed.

Research and Clinical

- Collaborates in the design and implementation of research diets.
- Collects and interprets nutrition-related data; participates in the publication and presentation of research findings to the scientific community and the lay public.
- May develop and conduct independent nutrition research projects.
- Informs research participants of the dietary aspects of research protocols and evaluates compliance.
- Attends conferences and educational symposiums to maintain current knowledge in management, finance, food-service, clinical nutrition, food science, and research methodology.
- Establishes and maintains positive interdisciplinary professional relationships to facilitate planning and implementation of research projects and effective participant nutrition care.
- Monitors and records food intake, and reinforces compliance with research protocols.
- May clarify dietary intake records and gather and prepare data for analysis.

QUALIFICATIONS

Education

- Bachelor's degree in foods and nutrition or related field.
- Master's degree in nutrition or related field highly desirable if position has research responsibilities.

Job Knowledge and Skills

- Must possess thorough knowledge of theory and practices of management, dietetics, and nutritional sciences.
- Must have good interpersonal skills.

Experience and Training

- Completion of an approved dietetic education program and registration by The American Dietetic Association.
- Three years of administrative experience.
- Exposure to clinical research preferred.
- Managerial or supervisory experience required.

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EXHIBIT 20-5

Position Description: Food Production Technician (or Research Dietetic Technician)

PRINCIPAL FUNCTION

Responsible for the preparation and service of meals to research participants on controlled nutrient diets in accordance with established methods and procedures.

DUTIES AND RESPONSIBILITIES

Administrative

- Precisely weighs, measures, and prepares food portions and ingredients for research meals using standardized methods and procedures.
- Prepares duplicate subject diets and/or aliquots for laboratory analysis.
- Assists in the development of recipes and menus to meet research protocol specifications.
- Inventories food and supplies; delivers requisitions; obtains assembled items.
- Maintains food safety and sanitation standards.
- Cleans all work areas in accordance with established procedures.
- Operates and maintains equipment according to prescribed safety and sanitation standards.
- May assist in training new employees or students.
- Maintains communication among subjects, nutrition research staff, nurses, and investigators.

Research and Clinical

- Instructs research subjects in the dietary procedures necessary for compliance with research studies.
- Monitors and records food intake; reinforces compliance with nutrition protocols.
- Uses nutrition software for the analysis of dietary records, research menus, and recipes.
- May write diets, obtain participant food preferences, take anthropometric measurements, and participate in the nutrition education of participants.
- May assist with data collection and data entry.

QUALIFICATIONS

Education

- Graduate of an approved dietetic technician program (or equivalent education and experience).

Job Knowledge and Skills

- Must have knowledge of basic food preparation, nutrition, food safety, and food composition.
- Must have good interpersonal skills.

Experience and Training

- One year related work experience preferred; computer experience desirable.

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EXHIBIT 20-6

Example of a Protocol Description for Protocol 809:
''Adipose Tissue Distribution and Adrenergic Mechanisms in Aging''

AIMS

The aims of this study are to compare values at baseline and after a weight-loss diet in young and elderly subjects with respect to measures of sympathetic nervous system activity; adrenergic receptor, lipolytic, and adenylate cyclase activity; glucose tolerance and insulin sensitivity; lipoprotein lipase (LPL) activity; and body fat distribution as measured by circumference and tomography.

OUTLINE OF PROPOSED RESEARCH

Thirty-three elderly (60-yr-old to 80-yr-old) male subjects will be recruited for the 3-month weight loss study (4 months including weight stabilization periods). Subjects must be healthy and taking no regular medications (other than multiple vitamins). They must be between 130% and 170% of ideal body weight, with adult-onset obesity. Subjects entering the study will follow an isocaloric diet similar to Step 1 NCEP of the American Heart Association diet (50% carbohydrate, 30% fat, 20% protein; 300 mg/day cholesterol; and 4 g/day sodium). Following the weight stabilization period, subjects will be instructed in a 1,000 kcal to 1,200 kcal weight-loss diet.

SUBJECT-DAYS

Each subject will participate in the study for 4 months. Twice as many people will be screened as are required for the study. Thirty-three subjects will be enrolled and 66 subjects (33 $\times$ 2) will be screened. Each screened subject will require 1 day for medical history and physical examination (66 $\times$ 1 day $=$ 66 days). Each enrolled subject will require : 1 day food record review, before and after weight loss (33 $\times$ 2 days $=$ 66 days); 1 day for fat biopsy, before and after weight loss (33 $\times$ 2 days $=$ 66 days); 1 day for plasma LPL before and after weight loss (33 $\times$ 2 days $=$ 66 days); and 3 visits per week for weigh-in and diet counseling (33 $\times$ 16 weeks $\times$ 3 days/week $=$ 1,584 days).

NUTRITION SERVICES

Type of Diet: During the 2-week pre- and post-assessment phases, subjects will be weight-stabilized on a constant diet as described under the outline. All meals will be cooked, packaged, stored, and distributed to the subjects as out-patients. Adjustments in caloric intake will be made as necessary using a liquid formula of the same composition as the constant diet. Following the weight stabilization period, subjects will be instructed in a 1,000 kcal to 1,200 kcal weight-loss diet. All diets will include a daily multivitamin and mineral supplement.

Nutritional Data and Analysis: Subjects will complete two 3-day food records, once during the preassessment phase and once during the weight-loss phase. These food records will be analyzed for kilocalorie and macronutrient content using a nutrient analysis software program (University of Minnesota Nutrient Data System, NDS).

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TABLE 20-8

Example of a Protocol Features Worksheet for Protocol 809: "Adipose Tissue Distribution and Adrenergic Mechanisms in Aging"

Protocol Features	Specifics
Research diet design	Constant diet provided as a 2-day rotating menu.
Resident or nonresident study	Nonresident (outpatient).
Number and length of study periods	Total time on protocol: 4 mo. Two 14-day controlled diet, weight-stabilization periods per subject (one at baseline and one following a 3-mo weight-loss period).
Number of subjects	n = 33 (11 subjects/year for 3 years).
Nutrients to be controlled	Isocaloric diet for weight-stabilization periods. Energy (kcal) distribution: carbohydrate 50%, protein 20%, fat 30%. Cholesterol 300 mg/day, sodium 4 g/day, dietary fiber 15 g/day.
Outpatient nutritional care	1,000–1,200 kcal weight loss diet, individualized for each subject. Follow-up counseling and weight monitoring 3 times/wk throughout the 3-mo (12 wk) weight-loss period.
Data collection instruments	Two 3-day food records (one at baseline and one during weight loss period). Data analyzed using NDS software for designated study nutrients.
Quality assurance procedures	Verify composition of diets by chemical assay of composites. Standardize procedures for collecting anthropometric and dietary data. Verify food preparation and storage temperatures. Verify weights of food items on research menus. Calibrate kitchen scales on regular basis and maintain log of results. Check accuracy of packing procedures for outpatient diets. Assess subject compliance with protocol using standardized procedures.
Protocol intensity ranking	High intensity.

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estimate professional and other dietary staff needs (see Tables 20-9 and 20-10).

Planning also must account for the designated hours of operation and coverage for staff vacations, holidays, weekends, and sick leave. It is important to be familiar with any employee union contracts because they may stipulate work hours, the tasks allowable for specific job categories, payment for temporary assignment to higher-level duties, employee rights in relation to disciplinary action and grievance procedures, reimbursement for uniforms, and vacation and holiday schedules. Other restrictions may apply if the research kitchen is located within a hospital.

Additional support may be available from nonnutrition personnel, with the caveat that all plans for sharing of responsibilities must be coordinated in advance with the appropriate supervisors or department heads. This may include nursing staff, who might help to facilitate a single shift of nutrition personnel by passing trays and reheating delayed meals, recording heights and weights, and serving one meal on weekends. Assistance with some cleaning tasks may also be available from the environmental services department.

Some institutions are able to use undergraduate or graduate students for certain kitchen and participant management activities, provided this occurs in the context of practicum courses and other educational programs. This valuable option is more likely to be feasible at universities that have undergraduate dietetics programs.

Multiple Concurrent Studies

Most clinical research centers and research kitchens are used simultaneously by many investigators, resulting in heavy demands on the dietary staff. Good communication among the investigators, recruiters, nurses, and laboratory and research kitchen personnel is essential for effective coordination of multiple projects. When carrying out multiple concurrent studies, the number of admissions allowed on each individual study will of necessity be limited. This number must be agreed upon with each investigator and recruiter before the study begins or the capacity of the facility may become overloaded.

A convenient way to facilitate planning and coordinate the activities of various personnel for concurrent projects is to develop individualized flow sheets for each study participant's schedule (Exhibit 20-7). This is particularly helpful if the participant is simultaneously involved in several protocols.

A good quality control system should be in place before investigators launch any study. For multiple concurrent studies, this quality control system must be designed specifically to prevent confusion and errors among studies, as well as among the diets for any one study. In some research centers, each participant is assigned a color and every food item can be marked with colored stickers or tape; for concurrent studies, the colors used for each study must be unique to that study. Similarly, letter and number codes also must be study-specific. Menu items for each study can be packaged and stored on separate shelves in the refrigerator or freezer. If certain items look the same but are made with different ingredients (such as cookies made with different fats), two employees can check each other and initial the quality control sheet before the food is served.

Study participants also can play a crucial role in quality control when multiple studies are being conducted. They can be given a copy of the menu, and when their tray is delivered, the staff member can double-check the tray as participants read their copy of the menu.

The foodservice supervisor or kitchen manager should make an overview of the expected workload for all of the studies and then set priorities for the coordinated production schedule. The work schedule must include the time needed to produce each recipe in each protocol; it is more efficient to prepare quantities that can be used for the whole study or at least several weeks. Recipe-based foods can be prepared ahead, frozen in appropriate portions, and weighed again on the day they are served.

It is essential that kitchen staff working on multiple concurrent studies be given particularly clear instructions regarding their responsibilities. A large erasable work calendar kept in the kitchen is a convenient way to organize this information in a central location; special instructions can be written on it and checked by the staff on a daily basis. It also is helpful to have individualized work schedules for each employee so all are aware of specific duties to be performed during their shift. This will streamline the logistics of food production and distribution and minimize errors.

Job descriptions for the foodservice workers engaged in multiple studies should be written so that staff can be universally trained, meaning that every kitchen staff member should know how to perform all tasks. This arrangement will permit the greatest flexibility because most research facilities are too small to assign one or two foodservice workers exclusively to each protocol. Job descriptions also must be written in explicit detail to avoid contract disputes if the employees are covered under a labor contract. There should be adequate staffing to cover vacation leave, sick leave, holiday leave, and 7-day-per-week kitchen coverage, and to accommodate the specific requirements of each protocol (Exhibit 20-8). Flexibility in staffing is an important aspect of planning for the workload. Quick alterations in work assignments may be needed to accommodate unexpected problems such as sickness, budget shortfalls, or recruitment delays.

The research kitchen staff need to work one of several shifts, depending on the complexity of the multiple protocols. Typical shifts are: 6:00 AM to 2:30 PM, 8:00 AM to 4:30 PM, and 10:30 AM to 7:00 PM. On occasion, when equipment needs to be shared, staff can be scheduled up until 11:00 PM to spread out the work and optimize the use of equipment.

Quality Assurance and Training

Quality assurance programs are critical to the performance of nutrition research units. Such programs protect the

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TABLE 20-9

Example of an Effort Estimation Worksheet for the Nutrition Research Manager for Protocol 809: "Adipose Tissue Distribution and Adrenergic Mechanisms in Aging"[1]

Tasks	Time Required per Yr[2]
Protocol design	10 hr
Research diet design	
@ 40 hr/diet × 2 diets	80 hr
Subject interviews	
@ 1 hr/subject × 11 subjects	11 hr
Data collection	
Instruction @ 0.5 hr/subject × 11 subjects	5.5 hr
Clarification @ 0.5 hr/food record × two 3-day food records/subject	11 hr
Individualized diet calculations	
First study period: @ 0.17 hr (10 min)/menu × 2 menus/subject	3.75 hr
Second study period: @ 0.17 hr (10 min)/menu × 2 menus/subject	3.75 hr
Add 25% for outpatient diets	2 hr
Nutritional care	
Calculation of weight loss diet @ 1 hr/subject × 11 subjects	11 hr
Instruction on weight loss diet @ 1 hr/subject × 11 subjects	11 hr
Other instruction @ 1 hr/subject × 11 subjects	11 hr
Follow up visits @ 0.25 hr/visit × 3 visits/wk for 12 wk	99 hr
Communications	
@ 0.5 hr/subject/wk × two 2-wk periods of weight stabilization	22 hr
Employee training	
Research methods	1 hr
Computers	1 hr
Compliance	0.25 hr
Quality assurance	1 hr
Employee supervision	
Orientation	0.5 hr
Menu design	1 hr
Recipe standardization	2 hr
Subject instruction	0.5 hr
Quality assurance	20 hr
Computer resources	2 hr
Data preparation	
@ 1 hr/subject × 11 subjects	11 hr
Total effort[3]	321.25 hr/yr
% Full-time equivalent (FTE)	15% (321.25 hr/yr/2080 hr/FTE = 0.15)

[1]Protocol 809 will enroll 11 subjects/yr for 3 years. For each subject, there are two 2-wk controlled diet periods/subject/yr.
[2]Effort is rounded to the nearest 0.25 hr.
[3]These figures do not include the additional time that is required for manuscript preparation. The effort expended on this activity will depend on the level of responsibility; primary authorship or co-authorship of multiple manuscripts may require 0.10 FTE or more. (Also see Conclusion: Presentation and Publication of Data; and Exhibit 20-9.)

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TABLE 20-10

Example of an Effort Estimation Worksheet for the Nutrition Research Staff[1] for Protocol 809: "Adipose Tissue Distribution and Adrenergic Mechanisms in Aging"[2]

Tasks	Time Required per Yr
Protocol development	5 hr
Recipe testing and standardization	60 hr
Nutritional care 1 hr/subject/wk × 11 subjects × two 2-wk controlled diet periods	44 hr
Dietary assessment Two 3-day food records/subject @ 0.33 hr (20 min)/recorded day of intake	22 hr
Quality assurance Develop protocols Monitor compliance @ 1 hr/subject/wk × two 2-wk controlled diet periods	 20 hr 44 hr
Communications 0.25 hr/subject/visit × 3 visits/wk × two 2-wk controlled diet periods	33 hr
Employee training	8 hr
Employee supervision 1 hr/protocol/day × 154 days	154 hr
Ordering and inventory 2 hr/wk × 44 wk	88 hr
Preparing and portioning food 0.75 hr/meal × 4 meals/day × 14 days/subject × two 2-wk controlled diet periods	924 hr
Sanitation 0.5 hr/day × 154 days	77 hr
Food safety 0.17 hr (10 min)/day × 154 days	26 hr
Outpatient study activities 0.33 hr (20 min)/day × 14 days/subject × two 2-wk controlled diet periods	102 hr
Total effort	1,607 hr per year
% Full-time equivalent (FTE)	77% (1,607 hr/2,080 hr/FTE = 0.77)

[1]Nutrition research staff positions usually are given the job title of senior research dietetic technician, administrative dietitian, or food production technician.

[2]Each year, Protocol 809 will enroll 11 subjects for two 2-wk controlled diet periods. For practical reasons, subjects are enrolled two at a time (ie, 5-6 pairs/yr, average 5.5 pairs/yr). The research kitchen thus will produce and deliver study diets for 154 days/yr (5.5 subject pairs/yr × 4 wk/yr × 7 days/wk).

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EXHIBIT 20-7

Example of a Scheduling Flow Sheet for Participants Enrolled in Multiple Concurrent Studies

Name: Doe, J.	Date of Birth:	Age (yr):
Date: 23-Jan-98	Height (cm):	Weight (kg):

PROTOCOL COMPONENTS

High-phosphorus research diet
Vitamin D infusion study (urinary vitamin D metabolite assays)
24-hr diurnal variation (blood calcium and phosphorus assays)
EDTA infusion
Calcium Infusion

Date	Hospital Day	Protocol Day	Scheduled Activities
14-Jan-98 1	Thur	0	Begin high-phosphorus diet at dinner
15-Jan-98 2	Fri	1	Start vitamin D infusion in AM
16-Jan-98 3	Sat	2	
17-Jan-98 4	Sun	3	
18-Jan-98 5	Mon	4	Start 24-hr urine collections
19-Jan-98 6	Tues	5	Assay urine for vitamin D metabolites
20-Jan-98 7	Wed	6	Obtain assay results; adjust vitamin D infusion rate
21-Jan-98 8	Thur	7	
22-Jan-98 9	Fri	8	
23-Jan-98 10	Sat	9	
24-Jan-98 11	Sun	10	
25-Jan-98 12	Mon	11	0800 start 24-hr diurnal variation study (hourly phlebotomy for Ca and P levels)
26-Jan-98 13	Tues	12	0800 end 24-hr diurnal variation study; calcium infusion 0800-1130 (hold breakfast)
27-Jan-98 14	Wed	13	
28-Jan-98 15	Thur	14	EDTA infusion study (hold breakfast)
29-Jan-98 16	Fri	15	
30-Jan-98 17	Sat	16	
31-Jan-98 18	Sun	17	
01-Feb-98 19	Mon	18	
02-Feb-98 20	Tues	19	
03-Feb-98 21	Wed	20	0800 start 24-hr diurnal variation study (hourly phlebotomy for Ca and P levels)
04-Feb-98 22	Thur	21	0800 end 24-hr diurnal variation study; calcium infusion 0800-1130 (hold breakfast)
05-Feb-98 23	Fri	22	
06-Feb-98 24	Sat	23	
07-Feb-98 25	Sun	24	
08-Feb-98 26	Mon	25	EDTA infusion study (hold breakfast)
09-Feb-98	Tues		Discharge

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EXHIBIT 20-8

Workday and Leave Coverage for Foodservice Staff Engaged in Multiple Concurrent Studies[1]

I. FTE required to maintain a basic staffing pattern of 3 foodservice personnel on duty 7 days/week.

Basic Coverage

One full-time equivalent (FTE) represents 8 hr/day × 260 working days/yr.
3.0 FTE/day × 7 days/week coverage/5 day standard work week = 4.2 FTE

II. FTE required to provide sick, holiday, and vacation leave for 4.2 FTE (see above):

Sick Leave (SL) Coverage

Based on an average absenteeism rate of 4.6% per year allowed by policy

260 working days/yr/FTE × 4.6% = 12 SL days/yr

12 SL days/yr × 4.2 FTE = 50.4 SL days/yr

$$\frac{\text{50.4 SL days/yr}}{\text{260 working day/yr/FTE}} = \text{0.19 FTE needed for absentee coverage}$$

Holiday Leave (HL) Coverage

Based on 12 holidays/yr/FTE

12 holidays/yr × 4.2 FTE = 50.4 HL days/yr

$$\frac{\text{50.4 HL days/yr}}{\text{260 working days/yr/FTE}} = \text{0.19 FTE needed for holiday coverage}$$

Vacation Leave (VL) Coverage

Employees earn VL days based on length of service.
The 4.2 foodservice personnel in the research kitchen would earn a total of 78 VL days/yr.

$$\frac{\text{78 VL days/yr}}{\text{260 working days/yr/FTE}} = \text{0.30 FTE needed for VL coverage/yr}$$

III. Summary

Total FTE level necessary to provide 3.0 FTE coverage 7 days/wk, including all paid leave:

Basic 7 days/week coverage	4.20 FTE
Sick leave coverage	0.19 FTE
Holiday leave coverage	0.19 FTE
Vacation leave coverage	0.30 FTE
Total	4.88 FTE

[1]Example courtesy of Karen Todd, MS, RD, General Clinical Research Center, University of California, San Francisco.

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physical and psychological well-being of the participants and ensure the scientific validity and integrity of the collected data. An integrated plan for continuous evaluation and improvement should be established for the preparation and delivery of research diets, for laboratory assays, and for the collection of dietary intake data. Stringent quality assurance begins with written policies and procedures, establishment of monitoring systems, and ongoing continuing education programs for employees.

A model for the development of a quality assurance program is provided in Figure 20-4; a sample procedure for implementation is shown in Table 20-11. Other aspects of quality assurance programs are discussed throughout this book (particularly in Chapter 18, ''Documentation, Record Keeping, and Recipes,'' Chapter 21, ''Performance Improvement for the Research Kitchen,'' and Chapter 22, ''Validating Diet Composition by Chemical Analysis'').

Well-chosen training programs for both new and experienced staff can be quite helpful. Considerable time and money can be saved and mistakes can be prevented by shortening the ''trial-and-error'' phase of the learning process. Some programs, such as those required by departments of health for hospital hygiene certification, are straightforward and readily available in many locations. It also may be desirable to arrange for additional training directed toward the specifics of research diet production in order to provide broader scientific perspectives for the daily work of the food-service workers. Such specialized classes are seldom available as part of regular degree programs in dietetics or nutrition, but they can be conducted effectively using a short-course format. Managers can develop their own on-site programs or can take advantage of courses open to the general community. (The Table of Contents for this book provides a list of topics that might compose such a training program. For examples of short course curricula, contact Director of Metabolic Kitchen, Pennington Biomedical Research Center, 6400 Perkins Road, Baton Rouge, LA 70808; and Director of Nutrition, Clinical Research Center, University of Indiana, 550 North University Boulevard, Indianapolis, IN 46202. See also MM Windhauser, A Ershow, Meeting the need for training on the design, preparation, and delivery of research diets, *J Am Diet Assoc,* in press.)

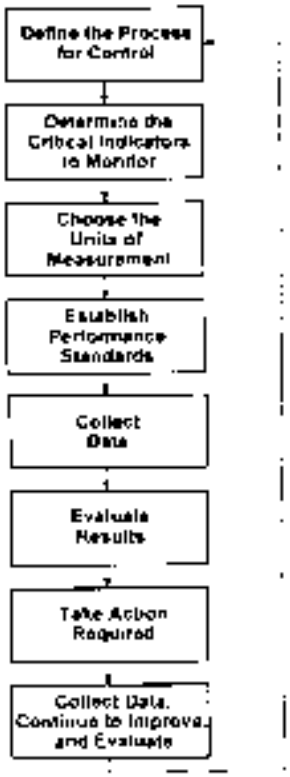

FIGURE 20-4. Quality assurance program: process flowchart.

Conclusion: Presentation and Publication of Data

Research studies are not truly completed until their results are published. The nature of controlled diet studies means that members of the nutrition research staff, particularly those who are registered dietitians or have otherwise completed undergraduate and graduate degrees, usually are familiar with the scientific goals of the study, the protocol methodology, and the data collection activities. Many of the individuals in these positions can make valuable contributions to writing groups engaged in data analysis and manuscript preparation. They also may be interested in presenting the results of the study at scientific and professional meetings. For those wishing to undertake such efforts, activities at this level should be important components of their job descriptions, with appropriate allotments of time (see Exhibit 20-9).

The authors gratefully acknowledge the contributions of Donna Nickel to the development of tables in this chapter.

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TABLE 20-11

Quality Assurance Program: Implementation Procedures

Quality Assurance Step	Procedures
Define the process for control	Develop standardized methods for the collection and analysis of dietary intake data. Use a specific procedure for each protocol.
Determine the critical indicators to monitor	Establish timelines for data entry. Establish guidelines for documentation of data obtained from participants. Establish tracking system to log receipt of data and completion of data analysis. Monitor results.
Choose the units of measurement	Monitor documentation errors (eg, accurate portion sizes, complete food descriptions, recipe yield etc), data entry logs, time lines, and results.
Establish performance standards	90% or better accuracy for documentation. 90% or better adherence to timelines. 10% or lower error rate for data entry and analysis.
Collect data	Conduct pilot study (eg, complete sample set of data or exercises using data collection instruments selected). Peer review and/or double entry of a subset of data. Collect random subset of data to monitor and designate timeline to be used.
Evaluate results	Assess the difference between the data collected and the performance standards.
Take action required	Provide additional training. Modify instruments as necessary. Complete quarterly documentation exercises.
Collect data, continue to improve, and evaluate	Monitor and verify controls.

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EXHIBIT 20-9

Preparing Manuscripts and Scientific Presentations

Preparing manuscripts and scientific presentations can be a highly rewarding aspect of conducting research. The required allotment of effort varies greatly from project to project, but there is no question that writing is a skill that improves with practice.[1] The following are some of the issues to consider in planning publication activities:

Clearly define the purpose of the paper and one's role in writing it.

Roles often are given titles that clarify responsibilities (eg, lead author, coauthor, section writer, data verifier).

Review the design and scientific scope of the nutrition project to be described.

Initially it is helpful to review the protocol and consider how the elements of the study design (eg, parallel-arm vs crossover design; number and time course of treatments; enrollment criteria; number and characteristics of participants; pilot studies and methods development) should be reflected in the various sections of the research report (rationale, methods, results, discussion).

In collaboration with a statistician, review the nutrition data that will be reported.

Standardized forms are invaluable for data entry and analysis, although they require time to be developed and tested before the study is implemented.

Review the literature.

The degree of familiarity with the subject matter of the report will influence the time and effort required for this portion of the paper.

Determine which data displays will be developed.

Appropriate visual communication of the quantitative data collected during the study is crucial to the message of the publication. The information displays (ie, tables, charts, graphs, and other figures) are more likely to reinforce the goals of the presentation or manuscript if the following points are considered:[2]

- The data should be presented in a way that is based on the cognitive task at hand. Most authors ask their audiences to make comparisons or assess changes.
- The display should help lead the reader toward the mechanisms and other types of causality that the authors plan to address in the discussion section. Time sequences can provide useful explanations of process but are not always the best way to clarify causal relationships.
- The displays should enforce visual and quantitative comparisons. These comparisons are made more effectively when the data or images are physically adjacent (ie, placed next to each other), rather than separated (ie, within different figures, pages, or slides). It is particularly difficult to compare data presented in multiple pie charts.
- The visual presentation and the original data should have the same degree of complexity. This helps to keep the cognitive message clear, honest, and free of clutter. For example, three-dimensional bar graphs should not be used to convey two-dimensional data (such as frequency counts).

Make realistic forecasts of time estimates.

Many experienced investigators allot one half-day per week (or 10% of effort) or more for working on manuscripts. Drafting and then polishing papers usually takes much longer than originally expected. It often is wise to estimate the time required, and then either double the figure, or round up to the next unit of time (eg, for four hours, round up to one day; for three days, round up to one week).

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[1]An excellent general guide to scientific writing is: Day RA. *How to Write and Publish a Scientific Paper.* 5th ed. 1998. Oryx Press, 4041 North Central Avenue, Phoenix, AZ 85012.

[2]These principles of information design are explained in a particularly insightful series of books by Tufte ER: *The Visual Display of Quantitative Information* (1983); *Envisioning Information* (1990); and *Visual Explanations* (1997); Graphics Press, Inc, Box 430, Cheshire, CT 06410.

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