

# Index

## A

- Abnormal laboratory values of participants
  - advising screenees about, 70, 71
  - referrals to health care providers following, 74
  - safety monitoring board's advice for, 69–70
- Activity factor (AF) for estimating total caloric need, 258, 260
- Ad libitum (ad lib) diet
  - advantages and disadvantages of, 143
  - food records for, 22–23
  - recipe calculation for, 23
  - software for, 20–21
- Adherence to research diets. *See also* Compliance issues in controlled diet studies
  - assessing, 4, 73–74
  - by children, 127–128
  - educating participants about, 324
  - ethics of addressing, 71, 74
  - monitoring, 7
  - objective methods for assessing, 194, 214
  - subjective methods for assessing, 104
- Administrative dietitian, position description for, 311
- Administrative expenses of controlled diet studies, 153
- Advertising to recruit participants for controlled diet studies, 68
  - advantages and disadvantages of, table of, 82
  - content of, 82, 119
  - costs of, 81, 153
  - effectiveness of, table of, 83
  - e-mail, 84
  - flier and poster, 81–83, 84
  - mass mailing, 81–83, 84
  - news stories for, 83–84
  - newsletter, 84
  - newspaper, 81, 82–83
  - personal contact/networking/word of mouth, 81–83, 84
  - placement of, 82–83
  - radio, 81, 83
  - sample advertisements for, 83
  - telephone, 81–82
  - television, 81, 83
- Agricultural Handbook No. 8 series (USDA), 23
- Alcohol consumption during controlled diet studies

- in holiday periods, 205–206
  - level of dietary control and, 151
  - in multicenter studies, 400–401
  - recording, 208
  - as underreported, 235
  - substituting for, 237
- Alcohol contribution to body's energy balance, 158
  - Aliquots
    - of composites for assay, 348, 354–355
    - used for primary measurements, discarding, 378
  - Alleles
    - associated with specific phenotype, 49
    - defined, 47, 56
    - transmission of, 49–50
    - unreported half-siblings identified by, 54–55
  - Aluminum content of foods
    - containers as affecting, 164
    - increased by low-sodium baking powder, 164
  - Amino acid powders, 223
  - Analyte exchange for compartmental interaction, 240
  - Analytical approach, assumptions of, 17
  - Animal studies, 2
    - contrast of human controlled diet studies and, 62
  - Anthropometric data
    - for children in controlled diet studies, 133–134
    - staff time to collect, 299
  - Antioxidants, research into vitamins as, 159
  - Apolipoprotein A-IV (ApoA-IV) gene, 51
  - Apolipoprotein B (ApoB) gene, 51
  - Apolipoprotein E (ApoE) gene, 50–51
  - Apples, browning of, 185
  - Artificial sweeteners
    - extraneous nutrients from, 208–209
    - relative sweetness of, 225
  - Ascertainment of study subjects in genetic research, 45–46
  - ASCII (American Standard Code for Information Interchange) format
    - defined, 21
    - reports in, 25
  - Association of Official Analytical Chemists (AOAC), 341
  - Atwater factors, 156–157
  - Authors of papers about controlled diet studies, advance agreement about, 74

- Auto Nutritionist IV CAMP program, 38

## B

- Balance studies. *See* Metabolic balance studies
- Bar code technology
  - applied in research kitchen management, 29–30
  - for food labels, 30, 186
  - products for, 41
- Barium sulphate as continuous marker for fecal collection, 387
- Basal body temperature (BBT), 111, 113, 115, 119
- Basal energy expenditure (BEE), Harris-Benedict equation for, 256
- Basal metabolic rate (BMR) equation, 256
- Baseline period of controlled diet studies, 144
- Beverages in controlled diet studies. *See also* Fluids and Water
  - caffeinated, 236
  - carbonated, 236, 237
  - considerations for protocol design of, 237
  - delivering, 196
  - extraneous nutrients in, 208, 236–237
  - food codes as preserving, 187
  - for formula diets, 213
  - intakes and allowances for, 234–236
  - in multicenter studies, 400–401
  - providing, 236–237
- Bias
  - acceptable, 370
  - defined, 369
  - method, 350, 356–357
- Biohazardous material handling, 73
- Biological markers, 49
  - chemical, 379
  - of completeness of collection, 245, 379, 383–384
  - costs of, 384
  - defined, 379
  - of dietary compliance, 380–382
  - in feces. *See* Fecal collection
  - natural nutrient, 379, 384
  - in urine. *See* Urine collection
  - uses of, 379, 380
- Blinding processes and participant identities, 15
  - computer applications to assist, 32
  - ethical issues in, 199
  - for formula diets, 212, 231

- goal of, 198
  - in multicenter controlled diet studies, 394
  - practical approaches to, 199–200
  - Blocks in parallel-arm study designs, 12–13
  - Blood collections during controlled diet studies, 387–388. *See also* Sample collection
    - from children, 135–137
    - consideration of need for, 63
    - limitations for, from women, 120
    - in stable isotope experiments, 250, 252
    - timing of, 387–388
    - training staff for, 387
    - venous vs capillary, 373
  - Blood pressure
    - affected by menstrual cycle, 116
    - DASH study of effects of dietary patterns on, 391
  - Body fat distribution, genes influencing, 44–45
  - Body mass index (BMI), equations for predicting REE using, 258
  - Bomb calorimeter, oxygen, 329–330
    - energy value of liquid formula determined by, 330
    - process of, flowchart of, 331
  - Bonferroni adjustment to p-values, 17
  - Brands of food
    - documenting study's, 265
    - specified to standardize diet in multicenter studies, 399
    - variance in nutrient content among, 23
  - Brilliant blue dye as intermittent marker, 386
  - Browser, Web, 35
  - Budgets of controlled diet studies
    - for chemical analysis, 364
    - computer applications for, 33
    - planning, 152–153
    - for recruitment of participants, 81
- C**
- Caffeine clearance affected by menstrual cycle, 117
  - Calcium chloride, 164
  - Calcium content of foods, 165, 189–190
  - Calculations needed for controlled diet studies, 24–25
  - Calorie levels
    - adjusting, 204, 205, 401
    - average, 147
    - for children in controlled diet studies, 132–133, 138
    - dietary techniques for managing, 260
    - estimating needed, 258, 396
    - food substitutions maintaining, 163
    - masking, 199–200
    - number in study of, 147
    - sample diet using average, 172
    - ways of determining, 156–158
  - Calorimetry
    - defined, 329
    - energy value determined by, 330
    - to monitor composition of formula diets, 329
  - Carbohydrate equivalents, 163
  - Carbohydrates in formula diets
    - complex, 225
    - properties of, 224
    - simple, 223–224
  - Carbon isotope <sup>13</sup>C
    - in formula diets, 221
    - growing plants isotopically labeled with, 189
    - natural concentrations in plants of, 251
  - Carbon isotope <sup>65</sup>C in intrinsically labeled kale, 190
  - Caretenoid content of foods, 159
  - Carmine red dye as intermittent marker, 386
  - Carryover effect, 11–12
    - defined, 144
    - investigated in crossover studies, 17
  - Case-control studies, 2, 3
  - CBORD Diet Analyzer for research diet design, 27, 38, 166
  - Cervical mucus
    - monitoring, 113, 115
    - Type E and Type G, 115
  - Checklists comparing tray against menu, 104
  - Chemical analysis, 329, 336–367
    - budget considerations of, 364, 365
    - checklist for, 349
    - costs of, 341
    - documentation of, 361
    - evaluating data of, 363–364
    - glossary of terms for, 349
    - goal of, 346
    - list of laboratories for, 362–363
    - methods of, 355–358
    - overview of, 347–348
    - reasons for, 336
    - paradigm for, 343–346
    - selecting dietary components for, 343
    - for validation of diet, 344–345, 363, 395, 397, 399
  - Chewing gum
    - chewing action from, 213
    - extraneous nutrients from, 208
  - Children
    - cognitive and psychosocial development of, 127–128
    - egocentricity of, 127
    - erratic appetites of, 135
    - height measurements of, 133–134
    - historical data about, 134
    - water intake of, 233–234
  - Children as participants in controlled diet studies, 6, 22, 126–140
    - adjusting study foods for, 128–129, 138
    - cooperation levels of, 127
    - enhancing compliance of, 137–138, 329
    - explaining expectations of study to, 69
    - favorite foods of, 129, 161
    - food intake measurements for, 134–135, 137
    - growth charts for, 133–134
    - incentives for, 72
    - informed consent for, 65, 67–68
    - need to include, 126–127
    - nutrient needs of, 132
    - physical hazards or health risks for, 131–132
    - recruitment and screening of, 136–137
    - research setting of meals for, 137
    - sample collection for, 135–136
    - stress on, 71
    - termination rate of, 136
    - time factors for, 135
  - Cholesterol absorption, 50
  - Cholesterol content
    - foods modified to reduce, 191
    - measurement of, 337, 341, 370–377
  - Cholesterol levels affected by menstrual cycle, 116
  - Chromium oxide as continuous marker for fecal collection, 387
  - Clinical trials, 2, 3–4, 394
  - Code of Federal Regulations (CFR), food regulations in, 191–192
  - Coinvestigators
    - physicians named as, 63
    - plan delineating duties of, 97
    - roles of, 62
  - Color coding research diets, 199–201
  - Coloring agents (inert dyes) as intermittent markers in fecal collections, 386
  - Committee on Amino Acids, National Academy of Sciences, 158
  - Compartmental model, 238–254
    - creating, 240–242
    - defined, 238
    - planned simultaneously with stable isotope studies, 250
    - software for, 242
    - uses of, 252
  - Compliance, participant
    - assessing and fostering, 102, 104–106, 401
    - biological samples collected as objective measure of, 379
    - calculating, 15
    - for formula diets, 214
    - increasing information to participants to improve, 329
    - involvement of family and significant others to ensure, 105–106

- in multicenter studies, 397, 398, 400–401
- normal serving sizes as enhancing, 160
- pregnancy as affecting, 120
- screening actions as indicators of, 96
- team approach to, 106
- Compliance issues in controlled diet studies, 16, 102–107
  - for children, 137–138, 139, 329
- Computer applications in controlled diet studies, 19–43, 165–176
  - for calculating research diets and ad lib dietary intakes, 19–27, 165
  - database management system (DBMS), 28
  - desktop publishing, 28
  - food and nutrition, product listing of, 38
  - for food labels, 31, 186–187
  - for food production sheets, 30–31
  - foodservice management, 29–33
    - general, 27–29, 39, 41
    - graphics, 29
  - for graphing children's growth data, 134
  - linear programming, 26, 176
  - meetings where vendors demonstrate, 35
  - for recipes, 31–32
  - resources for, 40
  - selecting, 165–166
  - spreadsheet, 26, 28, 33, 37, 39
  - statistical analysis, 28–29
  - word processor, 27–28, 32, 36
- Computer-assisted menu planning (CAMP) program
  - Auto Nutritionist IV, 38
  - IDC, 27, 38
  - in research, 26–27
  - sample of, 26
- Confidentiality issues
  - in genetic studies, 55
  - in reporting study results, 74
  - in storage of participant materials, 72
- Confounded designs, avoiding, 13, 119
- Containers, food
  - disposable, 152, 196, 276
  - glass and ceramic, 182
  - for meals eaten off site, 196–197
- Continuing Survey of Food Intakes by Individuals (USDA Survey Research Laboratory), 156, 167–168
- Control groups
  - in controlled diet studies, 13
  - in pilot studies, 149
- Control limits for chemical analysis
  - QCM values, 360
- Controlled diet studies, human
  - ad lib component stage of, 19, 20, 23
  - advertising for recruitment in, 68
  - application of quality control in, 327–330
  - areas of flexibility in, 100–101
  - budget planning for, 152–153
  - close-out of, 102, 108
  - computer applications in, 19–43
  - conflicts and problems during, 99, 100
  - core functions of, 302
  - costs of, estimating, 150–153, 189, 364, 365
  - data management for, 15–16
  - delivering diets for, 195–211
  - designing diets for, 155–178
  - early termination of, 65
  - emergency situations during, 101–102
  - enrollment in, fixed versus rolling, 147
  - ethical considerations in, 55, 62–75, 122
  - evaluation of, 106
  - exit interview following, 102–103
  - exit questionnaire for participants in, 106–107
  - feasibility of protocol for, 7
  - feeding component stage of, 19, 23
  - food preferences for ethnic groups in, 22
  - genetic effects in, 44–60
  - human factors of, 61–140
  - implementing, 15–16, 98–99
  - initiation stage of, 96–97
  - interim questionnaire for free-living participants in, 106
  - key aspects of conducting, 5–7
  - long-term, 24, 80, 93, 100
  - management of, 99–102
  - medications during, 70
  - misunderstandings about diet in, 99
  - monitoring progress of, 65
  - multicenter, 390–403
  - multiple concurrent, 147–148, 302, 304, 315, 318–319
  - multiple dietary treatments in, 146–147
  - outcome of, enhancing, 335–403
  - participants in. *See* Participants in controlled diet studies
  - personnel organization of, 302–315. *See also* Staff of controlled diet studies and individual positions
  - planned termination of, 73–74
  - planning, 10–15, 62–68, 142–154, 265–269
  - portion sizes in, 160–161
  - post-study corrective period for, 62–63
  - premature termination of, 73
  - providing beverages in, 236–237
  - publishing results of, 319, 321
  - purchasing list for, 172. *See also* Food purchasing for controlled diet studies
  - quality goals for, 323. *See also* Quality control
  - reporting results of, 74
  - research diets for. *See* Diets, research scheduled to avoid holidays and consider seasons, 148
  - scientific rationale of, 2–9
  - setting of. *See* Inpatient controlled diet studies and Outpatient controlled diet studies
  - statistical aspects of, 10–18
  - study design of, 1–60, 62–63, 118–119
  - twins in, 45–46, 51–53
  - types of, 4
  - water intake during, 234–236
  - weight gain or loss during, 204–205, 255, 260
- Controlled trials, randomized, 2, 3–4, 394
- Controlled-nutrient diets, maintenance of nutrients in, 143–144
- Cookies
  - chocolate drop, 286
  - lemon, 285–286
  - low-sodium, 281
  - oatmeal, 278, 284–285
  - protein-free, 217, 224
  - solid fat in, 226
  - sugar, 281–282
  - as unit foods, 260, 278
- Cooking and preparation techniques for controlled diet studies, 182, 184–185
  - for baked goods, 185, 190, 191
  - for beverages, 186
  - for condiments and spices, 186
  - for dry goods, 185
  - for meat, poultry, and fish, 182, 184
  - for mixed dishes, 186
  - for vegetables and fruits, 184–185
- Copper metabolism
  - <sup>65</sup>Cu isotope to study, 241–242
  - stable isotope tracers and compartmental modeling to study, 252
- Coronary heart disease, diet and, 5
- Courier service to deliver research diet meals, 197–198
- Covariates, incorporating, 17
- Creatinine as marker to ensure completeness of urine collection, 383–384
- Critical points, quality goals for, 325
- Crossover design in controlled diet studies, 4, 10–15
  - carryover effect in, 17
  - controlling for menstrual cycle phase in, 119
  - randomization scheme for, 16
  - sample size for, 12, 14
  - to study effects of carbohydrate content on glycemia and plasma lipoproteins, 391

- variation within participants used in, 15
- Cross-sectional studies, 3
- D**
- Daily record form for participants, 265, 270, 277
- Dairy food substitutions, 162–164, 190
  - in fat reduction or replacement, 190–191
- DASH study. *See* Dietary Approaches to Stop Hypertension (DASH) study
- Data analysis in controlled diet studies, 16–18, 119, 301, 377
- Data and safety monitoring board, role of, 65, 392–394
- Data collection
  - about food refusals, 329
  - guidelines for, 62, 99
  - menstrual cycle considerations in, 119
  - quality control for, 324–326
  - staffing and instruments for, 299, 306
  - standardizing aspects of, for children, 133, 138
- Data entry
  - of changes to study data, 72
  - in controlled diet studies, 15–16
  - edit checks for, 21, 24
  - minimizing errors in, 24
  - in nutrient-calculation programs, 20–21
- Data files
  - development of, 15
  - security of, 298
- Data management system for controlled diet studies, 15–16
- Data security, ensuring, 15, 298
- Data storage and archiving, 15, 72
- Database
  - adding foods to, 23
  - developing customized, 23
  - documenting, in controlled diet studies, 27, 265
  - features of, 21–24
  - food codes generated from, 186
  - food composition, 166–167, 234, 336–338
  - foods included in, 22–23
  - nutrient values for foods in, 20, 158–159
  - nutrients included in, 23–24
  - recipe, 31–32
  - recruitment monitoring, 81–82
  - selecting, 165–166
  - time-related, 24
- Database integrity during updates, 24
- Database maintenance, 24
- Database management system (DBMS)
  - to analyze menus, 166
  - converting food composition information into file for, 167
  - to generate food production sheets, 30
  - hardware support for, 167
  - uses in controlled diet studies, 28
- Database sparseness/completeness, 23
- Data dredging, 18
- Datasets
  - compiling complete, 24
  - maintained by USDA, 21–22
- Delivery of research diets, 195–211
  - cafeteria-style, 196
  - courier service for, 197–198
  - in multicenter studies, 400–401
  - off-site, 196–198
  - on-site, 195–196
  - prepared-tray method of, 196
  - problems and solutions in, 210
  - vending machines for, 198
  - of week's supply of food, 197
- DELTA study. *See* Dietary Effects on Lipoproteins and Thrombogenic Activity (DELTA) study (1992–1996)
- Desktop publishing uses in controlled diet studies, 28
- Deuterium stable isotope  $^2\text{H}$ , 251–252
- Diet classification system, St Jeor and Bryan, 143
- Diet composites, documenting, 265
- Diet cycle. *See* Menu cycle
- Diet development process, critical points in, 327
- Diet Formulation Questionnaire, 266–269
- Diet periods, duration of, 6
- Diet Planner program, 25
- Diet samples for compositing, 347, 350–354
- Diet study. *See* Controlled diet studies, human
- Diet summary, documenting, 264
- Diet types, 6, 142–145. *See also* Diets, research
  - ad lib. *See* Ad libitum (ad lib) diet
  - $^{13}\text{C}$ -neutral, 221
  - constant, 144, 149, 182, 307, 309, 313–314
  - controlled-nutrient, 143–144
  - depletion, 145
  - estimated, 143
  - formula. *See* Formula diet and Liquid formula diets
  - frozen, 186
  - habitual. *See* Ad libitum (ad lib) diet
  - high-fiber, 191
  - hyperosmolar, 221
  - liquid formula. *See* Liquid formula diets
  - modified food, 189–193
  - reference, 144
  - repletion, 145
  - run-in (stabilization), 144
  - weighed, 143, 307, 309
  - whole-food (conventional), 127, 182–186, 244, 338
- Diet-disease relationship, testing
  - epidemiologic studies for, 3
  - example of, 5
  - experimental studies for, 3–4
  - lines of investigation for, 4–5, 7
  - research methodology for, 2–3
- Dietary Approaches to Stop Hypertension (DASH) study
  - experimental diets of, 391
  - food procurement, preparation, and storage in, 400, 402
  - forms used in, 402
  - as multicenter controlled diet study, 390
  - organizational structure of, 393
  - outcome of, 392
  - planning by Diet Subcommittee of, 394–398
  - planning time line for, 401
  - sponsored by NHLBI, 390
  - statistical power of, 391
- Dietary cholesterol responsiveness, metabolic and genetic basis of, 50
- Dietary counseling
  - after studies, 205, 397
  - trials, 4
- Dietary Effects on Lipoproteins and Thrombogenic Activity (DELTA) study (1992–1996), 77
  - experimental diets of, 391
  - food procurement for, 400
  - food storage for, 400
  - as multicenter, collaborative controlled diet study, 390
  - organizational structure of, 393
  - outcome of, 392
  - pilot study of, 398
  - sampling plan for, 346
  - sponsored by NHLBI, 390
  - study diets of, 127
  - two protocols of, 390–391
  - women participants in, 85, 122, 390
- Dietary intervention, 141–262
  - delivering, 4, 302
- Dietary patterns affected by menstrual cycle, 117
- Dietary Reference Intakes (DRIs)
  - for children, 126, 132
  - to evaluate dietary adequacy, 155
- Dietary supplements, 165
- Diets, research. *See also* Adherence to research diets
  - archiving samples of, 230, 343, 346
  - chain of custody for materials in, 187
  - color-coding, 199–201
  - common problems of participants eating, 204–207
  - computer applications for calculating, 19–27, 176



- computer applications for designing, 165–176
- costs of, 150, 189
- delivering, 195–211, 329
- designing, 6, 155–178
- details in planning, 164–165
- development process for, 25–26
- as directing many foodservice tasks, 29–30
- linear programming to calculate, 26, 176
- liquid formula. *See* Liquid formula diets
- macronutrient distribution of, 170
- as mathematical problems, 26
- monitoring, 342, 345–346
- nutrient content table for, 170
- nutritional needs of women using, 122
- physical side effects of, 122
- producing, 179–194, 327–328
- requests for changes in, 100–101
- safety and sanitation standards for, 180, 187–189, 191–193, 196–197, 229
- sources of error and variance of nutrient content of, 339, 340
- staff understanding of, 97
- statistical reports for, 170
- summary evaluation of, 265
- tracking food production in, 186–187
- types of. *See* Diet types
- verifying composition of, 329, 336–367
- Diets, test, 143
- Digestible energy content, calculating, 242–243
- Dining areas
- atmosphere of, 297
  - lighting and use of color in, 297, 298
  - noise control in, 297
  - for serving meals, 296–297
- Disease, selection of study participants at risk for, 7
- Disposable containers for controlled diet studies, 152
- DNA sequence variation, identification and analysis of, 48–50
- Documentation of controlled diet studies, 264–270, 342, 361, 377
- Doubly labeled water method to measure energy expenditure, 251–252, 258
- Dropout rate in controlled diet studies, calculating, 15
- Dropouts
- avoiding, 101
  - discussing reasons for termination of, 101
  - effect on other participants of, 101–2
  - policies for managing, 16
- Dye markers for fecal collections, 245.  
*See also* Fecal collection
- E**
- Eating disorders, screening prospective participants for, 122
- Ecologic studies, 3
- Economy of scale for controlled diet studies
- in food purchases, 180
  - in number of participants, 147
- Edit checks for data entry, 21, 25
- Eligibility criteria for study participants, 69, 72, 77–80
- during screening, 88–89
- E-mail (electronic mail), 34
- as recruitment strategy, 84
- Emergency situations during controlled diet studies, 101–102, 205
- End-of-shift checklist, 272
- Energy balance equations, 256, 258
- Energy expenditure
- basal (BEE), Harris-Benedict equation for, 256
  - doubly labeled water to measure, 251
  - resting (REE), equations for, 256–259
  - total (TEE), equations for, 256–259
- Energy prescriptions, 255–260
- Energy requirements of formula diets, 214
- Epidemiologic studies, 3
- Equations. *See also* individual equations
- energy balance, 256, 258
  - predictive, 256, 258
- Equipment for controlled diet studies
- budgeting costs of, 153
  - contingency plans for breakdowns of, 148
  - for formula diets, 230
  - in research kitchens, 292–296
- Estradiol production, 111
- Estrogen production decreased during menopause, 116
- Ethical considerations in controlled diet studies, 55, 62–75, 122
- for children, 130–132
- Ethnic groups in controlled diet studies
- food patterns of, 161–162
  - food preferences of, 22
  - publication resources for, 162
- Evidentiary chain for specimens, 375–377
- Exit interview following study, 102–103, 397
- Exit questionnaire for participants, 106–107
- Expenses of controlled diet studies, tracking, 147
- Experimental studies, 3–4
- Extended pedigrees in genetic research, 45–46
- Extract blends, table of, 229
- F**
- Facilities for controlled diet studies. *See also* Dining areas *and* Kitchens, research
- human factors in, 297–298
  - for multicenter studies, 398–399
  - optimal use of, 147
  - planning, 163–164
  - tailoring study to, 148–149
- Family Feeding Study (FFS), prefeeding phase of, 127
- Family studies in genetic research, 45–46, 54–55
- Fat
- baked products to deliver dietary, 271
  - body weight reduction by reducing dietary, 258
  - chemical assays of, 356
  - DELTA study of effects on blood lipids and hemostatic factors of, 390
  - effects on blood pressure of, 391
  - food and products used to reduce or replace, 190–191
  - in formula diets, 225–226
  - masking, 199
  - principal fatty acids of, 227
  - saturated, 225–226
  - solid, 226
  - variance in foods' content of, 337–338
- Fat Tolerance Test Meal, 143
- Fecal collection, 384–387
- in balance studies, 246, 249, 252
  - challenges in making, 379, 384
  - continuous markers to ensure completeness of, 385, 386–387
  - extrinsic markers in capsules or food for, 386
  - freezing, 384, 385
  - intermittent markers to define the timespan of, 385, 386
  - procedures for, 384–385
  - real food markers (corn kernels, beets, and seeds) to mark diet intake period in, 386
  - sources of error in, 244–245
  - in stable isotope experiments, 250
- Feeding periods, length of, 148
- Feeding studies. *See* Controlled diet studies, human
- FIAS (Food Intake and Analysis System) nutrient calculation program, 38, 166
- nutrient-retention factors for, 23
- Fiber
- crude, 159
  - experimental foods to increase, 191
  - insoluble, 158, 191
  - inverse relationship of blood pressure level and amount of dietary, 391

- natural, as lacking in formula diets, 213, 216, 219
- soluble, 158, 191
- sources of, 219
- total dietary, 158–159
- Fiber intake recommendations, 158
- Filling cells, 119, 161–162
- Fisher's **Z** transformation, 53
- Fliers as recruitment strategy, 81–84
- Flowcharting a process, 325–326, 330–331, 345
- Fluid balance
  - affected by menstrual cycle, 117
  - weight changes affected by, 260
- Fluids, 232–237. *See also* Beverages in controlled diet studies *and* Water considerations in protocol design of, 237
  - daily patterns for intake of, 235
- Follicle-stimulating hormone (FSH)
  - levels as increasing during menopause, 115–116
  - production of, 110–111
- Follicular development, 111
- Food additives, 192–193
- Food allergies and intolerances, 206–207
  - of children, 132, 136, 206
  - food refusals because of, 204
  - for formula diets, screening potential participants for, 213
  - sources of information about, 207
  - substitutions for, 162–163, 190, 206
- Food analysis methodology, 338–342. *See also* Chemical analysis
- Food analysts, role in controlled diet studies of, 343
- Food and Drug Administration (FDA)
  - experimental foods managed as drugs by, 193
  - folic acid requirements of, 159
  - food additives regulated by, 192–193
  - food code guidelines of, 188
- Food choices
  - children's acceptance and preferences in, 128–130
  - for vending machine feeding systems, 198
- Food codes
  - assigned to foods, 186–187
  - guidelines as, 188
- Food composition
  - analysis of, 152, 244
  - of fresh food, variation in, 181–182, 345–346
  - tables of, 20, 337
- Food consumption guidelines, 200, 204, 401
- Food costs
  - computer applications for, 33, 39
  - variance among diets of, 151–152
- Food distributor, consistency of food content aided by using same, 180–181
- Food frequency questionnaires
  - beverages on, 235
  - level of dietary control as driving use of, 151
- Food intake
  - of children in controlled diet studies, 134–135, 136, 137
  - estimating, 256
  - spontaneous, 117
  - unauthorized, 244
- Food labels, 31, 186–187
- Food models, software for, 42
- Food preferences
  - assessed before study initiation, 161, 256
  - children's, 128–130
  - of ethnic groups, 22
  - of participants, 92, 129, 161, 329
  - of prospective participants examined during screen, 92
  - by region in multicenter studies, 399
- Food preparation procedures in research kitchen
  - cooking techniques in, 182, 184–186
  - of formula diets, 212, 228, 230
  - for multicenter studies, 398–399, 400
  - simplifying, 149
  - for take-out meals, 146, 197
  - weighing and measuring, 182–183, 185
- Food Processor (ESHA Research), 38, 166
  - for research diet design, 27
- Food production, critical points in, 327–328
- Food production sheets for cooks, automated, 30–31
- Food production technician, 309, 314
- Food purchasing for controlled diet studies
  - commercial packaged products vs from-scratch foods in, 152
  - dietary nutrient levels affected by, 338
  - donated foods vs, 399–400, 402
  - fresh foods, 181–182, 185
  - goals of, 151
  - in multicenter studies, 396, 399–400
  - overpurchasing quantities in, 179–180
  - of poultry and meats, 181
  - raw or cooked weight of food considered in, 179
  - safety factor for, 180
  - shelf life of foods considered in, 180–181
  - single-batch lots for, 152, 179, 181–182, 184, 186, 214, 299
- Food records
  - for ad lib components, 22–23
  - to estimate food intake, 256
  - food sources in, 180–181
  - level of dietary control as driving use of, 151
- Food refusals, 204, 329
- Food residues
  - bread to collect, 250
  - drinking the rinse to ensure intake of, 213, 244, 246, 250
- Food safety issues
  - for biomarkers, 386
  - critical points for, 328
  - for experimental foods, 191–193
  - in food purchasing, 180
  - for formula diets, 229
  - for multicenter studies, 396
  - in off-site delivery, 196–197
- Food storage for controlled diet studies
  - canned goods, 180–181, 296
  - capacity of facility important in, 180
  - composites, 355
  - dry goods, 152, 180–181, 220, 296
  - costs of, 152
  - frozen or refrigerated, 152, 180–181, 184–185, 230, 296, 315, 325, 400
  - maximum time for, 180–181, 230
  - minimizing, 149
  - for multicenter studies, 396, 400
  - nutrient constancy throughout, 179
  - planning for emergency, 148
  - shared spaces for, 296
  - for studies with children, 137
- Food subsets, 172–176
- Food substitutions in controlled diet studies, 161
- Food temperatures
  - danger zone, 230
  - during homogenization of samples, 354
  - for potentially hazardous foods, 327
  - temperature-sensitive strips to monitor take-out meal, 197
- Food values, estimated, 23
- Foods
  - bland, 161
  - browning of, 180, 185
  - core, 172–174, 176
  - disliked, 161, 162
  - emulsification of, 226, 228
  - free. *See* Free foods
  - gross energy of, calculating, 156
  - key, 160
  - modifiable, 172–176
  - modified and experimental, 189–193
  - mouth feel of, 199, 228
  - portion sizes of, 160, 237, 328
  - potentially hazardous, 328
  - selected for research diets, 160–165, 181–182
  - spilled, 99, 196, 210

- in take-out meals. *See* Take-out meals
- thermic effect of, 243
- unit. *See* Unit foods
- variability of, controlling, 180–182, 399
- weights of, 179, 182–184, 186, 196, 272–274, 399
- Foodservice expenses, budgeting, 153
- Foodservice management, computer-assisted, 29–33
- Foodservice workers. *See* Staff of controlled diet studies
- Forms
- in DASH study, 402
  - design and testing of, 15
  - for multicenter studies, 401–402
  - out-of-range values controlled for, 16
  - for planning, 265–269
  - quality control, 265, 274–276
  - reviewed for completeness, 16
  - screening, 88
  - for take-out meals, 265, 276
- Formula diets, 142, 151, 176, 188–189, 212–231. *See also* Liquid formula diets
- advantages of, 212, 231
  - calculating, 214, 217, 218, 220, 224
  - calorimetry to monitor compositional consistency of, 329
  - choosing suitable ingredients for, 226
  - color of, 228
  - costs of, 212, 214
  - commercial, 214
  - deciding to use, 212–213
  - designing, 214–221
  - disadvantages of, 212–213, 231
  - dry powdered, 214
  - eating techniques for, 213
  - equipment for, 230
  - flavor of, 228, 229
  - gastrointestinal discomfort from, 213
  - laboratory analysis to verify composition of, 221
  - meeting nutrient requirements and study goals using, 214, 216–221
  - organoleptic aspects of, 228
  - presenting, 213–214
  - producing, 226–230
  - recipes and preparation techniques for, 212, 228, 230
  - research applications of, 231, 248–249
  - sanitation issues for, 214, 230
  - single-lot purchases of, 214, 228
  - site-produced, 214
  - solid, 212, 214–216
  - sources of nutrients in, 222–226
  - storage of, 214, 230
  - time analysis estimates for staff for, 307, 309
- Formulations of food products, changes in, 24
- Free foods
- for children, allowing, 135
  - for formula diets, 213
  - for lipid studies, 200
  - for multicenter studies, 400, 402
  - specifying limits on, 146
- G**
- Garnishes, extraneous nutrients from, 208
- Gastrointestinal function affected by menstrual cycle, 117
- General Clinical Research Centers (CCRCs) (NIH), 302, 304
- Patient Satisfaction Questionnaire of, 332
- Genes
- candidate, 47, 50–51, 56
  - influencing obesity and body fat distribution, 44–45
  - interactions between nutrition and, 44
  - for lipoprotein metabolism, 50
  - localizing and identifying, 47–48
  - schematic of typical, 48
- Genetic analyses, initial, 45, 47
- Genetic bit analysis (GBA), 49
- Genetic effects in controlled diet studies, 44–60
- Genetic polymorphisms, 48–50
- Genetic research
- ethical and social issues in, 54–55, 67
  - glossary of terms for, 56
  - misspecification of family relationships in, 54
  - study designs in, 45–50
- Genome-wide scan for localizing genes, 47, 48, 56
- Genotype information, 49
- Graphics software uses in controlled diet studies, 29
- Growth data for children in controlled diet studies, 133–134
- H**
- Habitual dietary practices and patterns of participants examined during screening, 92–93
- Hard candy, extraneous nutrients from, 208
- Harris-Benedict equation for basal energy expenditure (BEE), 256
- Hazardous Analysis Critical Control Point (HACCP)
- concept, 328
  - food safety guidelines, 187–188
- Hepatitis B vaccinations of staff, 73
- Heritability analyses, 45
- Heritability estimates, 51–54
- High-density lipoprotein cholesterol (HDL-C), response to diet of, 51. *See also* Dietary Approaches to Stop Hypertension (DASH) study
- High-density lipoprotein (HDL) turnover studies, 51
- Holiday periods
- advance planning for meals during, 205
  - exceptions to research diets for, 205–206
  - scheduling controlled diet studies to avoid, 148, 205
- Homogenization of food samples for assay, 347, 354, 355
- Homogenizers, 230
- Hormonal status of women, 109–116, 119–120
- confounding effects from, 209
  - screening questionnaire for, 121
- Hormone replacement therapy (HRT), 116, 118
- screening prospective participants for use of, 120–121
- Hot flashes, 116
- Human factors of controlled diet studies, 61–140
- Human Genome Project, 56
- Hunger problems of participants, 204, 244
- Hypothesis in human controlled diet studies
- creating testable, 5
  - study design to test, 5–6
- I**
- Illnesses of participants
- ethical considerations for, 64–65, 70
  - food consumption during, 206
  - termination from study because of, 206
- Implementation of controlled diet studies, statistical issues in, 15–16
- Imprecision of measurements, 369–370
- Incentives for participants. *See also* Payment of participants in controlled diet studies
- as building morale, 102
  - for children, 136–137, 329
  - to increase compliance, 329
  - in multicenter studies, 397
- Informed consent, 74
- for children, 65, 67–68, 131
  - for dependent groups, 67–68
  - development of concept of, 65
  - form for, demands originally not specified in, 63
  - as foundation of ethical conduct of study, 68
  - for future analyses of blood or tissue samples, 67
  - for genetic studies, 55, 67
  - IRB requirement for, 91

- liability for health problems specified in, 64–65, 70  
 sample document for, 66–67  
 termination criteria for participants specified in, 65, 69  
 weight issues specified in, 205  
 for women, 120
- Inheritance patterns, 47
- Inpatient controlled diet studies  
 children in, 126  
 expense of, 146, 151  
 level of dietary control in, 151  
 protocol intensity rating guide for, 301  
 staffing for, 299
- Institutional review board (IRB)  
 approval of study by, 63–64, 65–68  
 informed consent document from participants required by, 91, 120  
 modifications and additions to protocol reviewed by, 68, 72  
 need for invasive procedures assessed by, 63  
 oversight over study protocols of and protection of subjects of, 62, 130–131  
 rules for payment of participants specified or assessed by, 72, 86  
 safety issues addressed by, 120  
 time line for approval by, 97
- Intent-to-treat paradigm, 16
- Interactive Diet Construction (IDC) CAMP program, 27, 38
- Interim questionnaire for participants, example of, 106
- International Network of Food Data Systems (INFOODS), 162
- Internet service provider (ISP), 34
- Intervention studies, 5  
 influence of genetic factors on body fat storage and mobilization as subject of, 45
- Investigators in controlled diet studies.  
*See also* Principal investigators in controlled diet studies  
 avoidance of overburdening staff as responsibility of, 73  
 exclusion of prospective participants by, 70  
 policy on participant absence set by, 70–71  
 promises made by, fulfilling, 74  
 protocol modifications by, 68, 72–73  
 protocol procedures tested on, 63  
 safety monitoring committee provided participant information by, 64  
 wholesomeness of food as responsibility of, 72
- Interview forms, documenting, 265
- Interviewer checklist for explaining study conditions to participants, 67  
 sample, 68
- Invasive procedures during controlled diet studies, 63
- Inventory, computer applications for, 33
- Iron fortification in cereals, 165
- Isotopically labeled plant products, 189–190
- J**
- Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) standards on quality assessment, 332–333
- Journals  
 food analysis methods and results, 356  
 trade and professional, 191, 193
- K**
- Key nutrients, 343–344
- Kitchens, research, 290–298, 323–333  
 adapted for studies with children, 137  
 aisle space in, 292  
 contingency plans for equipment in, 148  
 counterspace in, 292, 294  
 countertops of, 295  
 formula diets prepared in, 214  
 layout of, 291–294  
 lighting in, 297–298  
 managed by senior research dietetic technician, 303, 306  
 maximizing efficiency of, 149, 294, 309  
 for multicenter studies, 398  
 for multiple concurrent studies, 315  
 planning, 290–292  
 production areas of, 291  
 security issues for, 298  
 use of students and volunteers in, 151  
 ventilation and climate control of, 294–295, 297  
 wall and floor surfaces of, 295  
 work areas in, 292–295  
 work priorities in, 298  
 waivers of food purchasing policies for, 191
- Kool-Aid® soft drink mix, nutrient content of, 165
- L**
- Labeling samples, 15
- Labels  
 bar code, 30, 186  
 food, 31  
 inventory, 33–35  
 for meals delivered by courier, 198  
 temperature-sensitive, 189
- Laboratory  
 for composite assays, 356–358  
 for food analysis, 362–363, 399  
 for multicenter studies, field center vs centralized, 392–394  
 turnaround time for processing in, 376
- Laboratory error. *See also* Variance contributing to overall variance, 374–375  
 defined, 369  
 minimizing, 368
- Laboratory expenses of controlled diet studies, budgeting, 153
- Laboratory mean, 369
- Laboratory performance, limits of acceptability of, 370–371
- Laboratory staff processing participants' samples, communication with, 106, 376
- Lactating women  
 controlled diet studies on, 120, 122  
 water intake of, 233, 234, 236
- Lard, 225, 226
- Linear programming  
 to calculate conventional food research diets, 176  
 to calculate formula diets, 26, 176  
 in design of defined diets, 37
- Linkage analyses, 47, 56
- Linkage disequilibrium  
 defined, 56  
 markers in, 49
- Lipoprotein measurement, 371–375
- Liquid formula diets. *See also* Formula diets  
 appropriate uses of, 6, 142  
 archiving samples of, 230  
 bomb calorimetry to measure energy value of, 330, 343  
 compliance problems with, 214  
 cost effectiveness of, 150  
 duration of use of, 213  
 sample protocol description for, 312  
 texture of, 228  
 used with solid foods, 214  
 volume and number of daily meals for, 213  
 water intake in, 237
- Local area networks (LANs), 34
- Luteinizing hormone (LH)  
 BBT to test concentration of, 113  
 ovulation kits' use of, 112  
 peak of, 113  
 production of, 110–111  
 surges during ovulation of, 112, 115
- M**
- Macronutrients in formula diets, 214
- Malaise caused by invasive procedures, 63
- Masking in controlled diet studies. *See* Blinding processes and participant identities



- Mass mailings as recruitment strategy, 81–84
- Meal plan for children, adding snacks to, 133
- Meals
- behavior of families eating on site, 137
  - delivery to participants of, 99, 197–206
  - emergency, 205
  - ethics of providing participants with wholesome, 72
  - for liquid formula diets, 213
  - load test, 143
  - for multicenter studies, 396
  - reassessed after tray checks, 105
  - skeleton, 196
  - task analysis of production time for, 309, 313–314, 316–317
  - take-out. *See* Take-out meals
- Measurement errors, 350
- Meat substitute products, 190
- Medical questionnaire for prospective participants, 90–91
- Medications during controlled diet studies
- for children, 138
  - ethical considerations for, 70, 74
  - extraneous nutrients from, 209
- Menarche, 109
- Menopause
- defined, 115
  - screening of prospective participants for, 120
  - signs of, 115–116
  - surgical, 116
- Menstrual calendars, 113–114, 119, 120
- Menstrual cycle
- BBT to monitor, 113
  - controlling for, 118
  - data collection affected by, 119
  - dietary effects on, 119
  - educating study participants about, 120
  - effects of age on, 110
  - effects of vegetarian diet on, 118
  - effects on physiologic systems of, 116–117
  - electronic devices to monitor, 113
  - follicular phases of, 110–111, 113, 116, 118–119
  - limits on blood collections from women having regular, 120
  - luteal phase of, 110–112, 116–117
  - normal, 109–110
  - postmenopausal, 116
  - study design considerations of, 118–119
- Menstrual phase
- data obtained to define, 119
  - identification methods, 110–115
- studies' methods of identifying, 117–118
- studying subjects in specific phase of, 120, 122
- Mentally ill or retarded persons as participants in controlled diet studies, 65
- Menu composite, 354
- Menu cycle
- composite of, 345, 354
  - defining, 395
  - fecal collections timed for, 245
  - length of, 148
  - nutrient summaries for, 264–265
  - reviewing, 175
  - rotation of, 143, 146
- MENU Database Planning Software (Database Manager), 27, 38, 166
- Menu planning
- computer-assisted, 25–27
  - for multicenter studies, 395, 399, 401–402
- Menus
- adapted for children in controlled diet studies, 129–130
  - assessment of usual dietary intake in designing, 256
  - computer applications for preparing, 32–34, 36, 37, 166–172
  - food subsets to develop, 172–175
  - master, documenting, 265
  - master, unmasked kitchen, 200, 201–203
  - nutrient content lists for, 170
  - in pilot studies, 149, 344
  - prefeeding validation of, 342, 343–345
  - provided to participants prior to initiating participation, 98–99
  - reviewing and verifying composition, 175, 274
  - sample participant form for, 265, 274
  - staff trying out, 151
  - 24-hour, 142
- Metabolic balance diet, 144
- fundamental principle of, 144
- Metabolic balance studies, 242–249
- adaptation to diet in, 243
  - equations used in, 242–243
  - example of procedures and outcomes of, 246–248
  - food consumption techniques for, 200
  - food preparation for, 244
  - fundamental components of, 242
  - liquid formula diets in, 142
  - nitrogen, 245–249
  - number of participants in, 243
  - nutrient content of, 20
  - practical considerations for, 243–246
  - sources of errors in, 243–246
  - stable isotopes used to enhance, 252
  - 24-hour menu for, 142
  - uses of, 240
- Metabolism
- intermediate, 238
  - modeled using stable isotopes, 250
  - physiologic pools in, 239, 240
- Metabolizable energy content, calculating, 243
- Method bias, 350, 356–357
- Methylene blue dye as intermittent marker, 386
- Mifflin-St Jeor equation for resting energy expenditure (REE), 256, 260
- Migrant studies, 2
- Minerals
- balance study of, in elderly males, 246–248
  - deionized water used in studies of, 185, 186, 207–208
  - differences in soil content of, 190
  - effects of cooking and handling foods on their, 168
  - elimination of unabsorbed, 238–240
  - environmental contamination of, 244
  - extraneous nutrients from, 207
  - in formula diets, 216
  - formulating research diets for content of, 158–159
  - supplements containing, 196, 207
  - from water, 237
- Minimum detectable difference, 14
- Minorities, recruiting, 85
- Moisture content of foods for assay, nutrient values affected by, 363–364
- Morale of participants, 102, 147–148, 197. *See also* Incentives for participants
- Muffins
- as pre-prepared foods, 399
  - as unit foods, 260, 278–279
- Multicenter controlled diet studies, 390–403
- activities of, 397–398
  - centrally prepared diets for, 391
  - close-out period of, 398
  - costs of, 394, 395, 397
  - examples of, 390–391
  - implementing, 398–402
  - organization and operation of, 392–394
  - planning, 395–398, 401–402
  - quality control in, 397
  - scientific rationale for, 391–392
  - uniqueness of, 402
- Multiple Risk Factor Intervention Trial (MRFIT), 77
- Multiplicity in tests of significance, 17–18
- N**
- National Agricultural Library software lists maintained by, 35
- Web site of, 37

- National Center for Health Statistics (NCHS), growth charts of, 133
- National Cholesterol Education Program (NCEP) Guidelines to compare fat type and amount to dietary goals, 156
- National Cholesterol Education Program (NCEP) Laboratory Standardization Panel, 370–371
- National Health and Nutrition Examination Survey III (NHANES III) growth chart data of, 133 intake records of, 21
- National Health and Nutrition Examination Surveys, estimates of nutrient intake in, 156
- National Heart, Lung, and Blood Institute (NHLBI), DELTA and DASH studies sponsored by, 390
- National Institute of Standards and Technology, 341
- National Institutes of Health (NIH) guidelines for inclusion in funded research, 85, 109, 126–127
- National Nutrient Databank (NND), 166
- National Sanitation Foundation, 284, 295
- Nationwide Food Consumption Survey, 21
- Net energy, calculating, 243
- Networks, computer, 33–35, 37
- News stories for recruitment of participants, 83
- Newsletter advertising as recruitment strategy, 81–84
- Newspaper advertising as recruitment strategy, 81–83
- Nitrogen content of food sample, 358–359 of urine to assess dietary compliance, 382
- Nitrogen loss, sources of, 245–246, 247–249
- Nitrogen-to-protein conversion factors, 157
- Noncompliance, participant by children, 138 documenting, 265, 270, 277 example of managing, 101 in multicenter studies, 401 signals from participant about, 105
- Nutrient balance, calculating, 242
- Nutrient Data Base for Standard Reference (SR-12). *See* USDA Nutrient Data Base for Standard Reference (SR-12)
- Nutrient database, 20, 166–167 information to include about, 27
- Nutrient digestibility, apparent and true, 242
- Nutrient intake calculating, 19–20, 155, 165, 244 current US population, 156 determining, 156–158 different from study goals, reasons for, 138 measurement of, errors in, 244–246 medications as source of, 138 report of daily, 24 software for calculating, 19–27, 165 standard for adequacy for children of, 133 for water, 235–236
- Nutrient intake questionnaires, single vs multiple, 301
- Nutrient parameters, assay profiles for, 344, 364
- Nutrient summary, documenting, 264–265
- Nutrient-calculation software, 20–25, 165–169 developing in-house, 25 diet list file in, 167, 169 edit checks for data entry in, 21 entering demographic information in, 21 entering food amounts in, 21 entering food descriptions in, 20–21 food composition file in, 167, 169, 171 generating nutrient value using, 167 merging diet list file and food composition file for, 167, 169 moisture/fat gain/loss file for, 167, 171 nutrient retention file for, 167, 171 production sheets downloaded to word processor from, 32 recipe calculation in, 23, 167 report of daily nutrient intake in, 24 selecting, 27 sort features of, 24 summary report from, 167
- Nutrient-nutrient interactions, 7
- Nutrients calculating dose of, 7, 271–289 controlling extraneous sources of, 6, 164, 207–209 lack of accurately analyzed data for, 159 movement in body of, 239, 244 supplemented with vitamins and minerals, 156 variance in amounts of, 337
- Nutrition, interaction between genes and, 44
- Nutrition Data System (NDS) (Nutrition Coordinating Center), 38, 166 nutrients for cooked ingredients included in, 23
- Nutrition history for prospective participants, 92
- Nutrition Labeling and Education Act (NLEA) (1990), 338, 356
- Nutrition research manager position description for, 305, 311 research diet tasks of, 303, 306, 307 responsibilities of, 303 sample effort estimation worksheet for, 316 time analyses for research diet tasks of, 303, 306, 307
- Nutritionist III, recipe nutrients analyzed by, 278–279, 287–289
- Nutritionist IV (First Databank) for research diet design, 166
- Nutritionist V (First DataBank), 38 for research diet design, 27
- Nutritive Value of Foods (Home and Garden Bulletin 72), 21
- O**
- Obesity genes influencing, 44–45, 511 permission for participants in studies of, 62–63
- Observational studies, 3, 5
- Off period of diet study, 144
- Office for Protection from Research Risks (OPRR), 64
- Oils customized production of, 225 in formula diets, 225–226 principal fatty acids of, 227 specialty, 227
- Older adults as participants, recruiting, 85–86
- Oligonucleotide ligation assay (OLA), 48–49, 56
- Oral contraceptives (OCs) caffeine clearance affected by, 117 folate, B-12, B-6, and riboflavin increased for women taking, 159 screening prospective participants for use of, 120 types of, 115
- Orientation to controlled diet studies of participants, 98–99 of staff, 98
- Osmolality, 219, 221, 245, 381
- Outcome data access of data and safety monitoring committee to unblinded, 65 interpretation of, 120
- Outcome variables, selecting, 6–7
- Outliers, data, 17
- Outpatient controlled diet studies children in, 126 design elements classification guide for, 300 estimating energy experiments, 146 food safety issues for, 189, 196–197 food selection for, 146, 204 levels of dietary control and costs of, 151 maintaining body weight during, 146 planning considerations for, 146 protocol intensity ranking guide for, 301

- reasons to consider, 146
- sample protocol description and worksheet for, 312, 313
- staffing for, 296
- trend toward, 297
- Ovulation
  - confirming occurrence of, 113
  - detecting, 110–111, 113
  - documenting occurrence of, 110
  - hormonal surges during, 113
- Oxygen stable isotope <sup>18</sup>O, 249–250
- P**
- Para-aminobenzoic acid as marker, 245, 381, 383, 384
- Parallel-arm design in controlled diet studies, 4, 10–13
  - consideration of menstrual cycle phases in, 119
  - sample size for, 12, 14
  - variation among participants used in, 15
- Participants in controlled diet studies, 76–95
  - accommodating special needs of, 93–94
  - accommodating work schedules and routines of, 146
  - assigning study numbers to, 375
  - assignment of, 4, 15–16
  - in balance studies, 243
  - burden of, factors in, 63, 70, 74, 89
  - children as, 6, 22, 65, 67–69, 72, 126–140, 161
  - common problems of, 204–207
  - compliance of. *See* Compliance issues in controlled diet studies
  - confidentiality of. *See* Confidentiality issues
  - consequences for eating meals at study site for, 69
  - as coproducers of services, 331
  - demographic subgroups of, 6
  - dependent people as, 67–68
  - disclosing purpose of study to, 69
  - disease status of, 6
  - disseminating information to, 102
  - eating techniques for, 200, 204
  - economies of scale for number of, 147
  - elderly, 161
  - eligibility criteria for, 69, 72, 77–80, 88–89
  - emotional problems and stress of, 71, 74
  - ethical obligations to, 70–72, 74
  - ethnic groups as, 22, 85
  - exclusion criteria for, 54, 70, 91
  - exit interviews of, 73–74, 397
  - exit questionnaires for, 106–107
  - explanation of study to, 68–69, 91, 97, 98
  - facilities at home for storing and heating food of, 93
  - faculty as, 73
  - food differences for, 180
  - food preferences of, 92, 129, 161, 329
  - on formula diets, working with, 213–214
  - free-living. *See* Outpatient controlled diet studies
  - habitual lifestyle information about, 91–92
  - heating food of, 93
  - identifying target groups of, 85, 86
  - illness of, 206
  - individualized schedule flow sheets for, 315, 318
  - information provided to, 106, 329
  - inpatients as, 86
  - interaction patterns of, 92
  - interim questionnaire for, 106
  - managing, 96–108, 120, 122
  - mediating issues among, 100
  - medical questionnaire for, 90–91
  - menopausal status of, 116
  - mentally ill or retarded persons as, 65
  - minorities as, 85
  - morale of, 102, 147–148, 197
  - motivation of, 71, 73–74, 86, 102
  - non-English-speaking, assistance for, 67, 85
  - number in sample of, 6, 10–12, 14–15
  - nutrition history for, 92
  - older adults as, 67, 85–86
  - orientation of, 98–99, 397
  - payment of. *See* Payment of participants in controlled diet studies
  - physical activity questionnaire for, 93
  - in pilot studies, 149
  - prisoners as, 65
  - privacy for, 72, 74
  - “professional,” 86
  - recruiting, 54–55, 64, 68–70, 76–87
  - refrigerator or freezer requirements for, 146
  - regular interviews to reveal problems with foods, 105
  - reporting lifestyle changes of, 99, 100
  - requests for changes in protocol by, 99–100, 102
  - response to treatment of, 375
  - responsibility for welfare of, 62, 64, 65, 88
  - results of study given to, 398
  - rights of, 55, 65, 73–74, 101
  - safeguarding information about, 375–376
  - satisfaction of, quality service to ensure, 330, 332
  - screening of, 69–70, 77, 80, 87–95, 119–120, 122
  - screening questionnaire for, 120–121
  - selecting, 6–7, 91–94, 96
  - students as, 73
  - system for identifying and blinding, 15
  - termination from study of, 65, 67, 69, 71, 101, 401. *See also* Dropouts
  - travel requirements and days away from study of, 70–71, 93–94
  - trust between staff and, 99, 324
  - variance among and within, 15
  - women as. *See* Women as participants in controlled diet studies
- Patient Satisfaction Questionnaire (GCRC), 332
- Payment of participants in controlled diet studies
  - budgeting costs of, 153
  - for children, 136
  - compliance and retention improved by, 120
  - ethical considerations of, 71–72
  - IRB assessment of appropriateness of, 72, 86
  - tied to sample collections, 72, 102
  - “Pending IRB” document, 64
- Permanent study file, information in, 264–265
- Photographs of participants, use of, 74
- Physical activity questionnaire for prospective participants, 93
- Physician referrals as recruitment strategy, 81–84
- Physicians
  - as coinvestigators or consultants in controlled diet studies, 63
  - in safety monitoring committees, 64
- Phytic acid, 190
- Pica, 209
- Pilot studies
  - advantages of, 150
  - to check homogenization of composites for assay, 355
  - defined, 149
  - DELTA study, 398
  - evaluation of, 150
  - of participant recruitment and screening procedures, 94
  - reasons for conducting, 149, 344
- Pilot test of protocol, 97
- Planning controlled diet studies, 10–15, 142–154
  - contingencies in, 107
  - ethical considerations in, 62–68, 122
  - feeding phase considerations in, 145
  - forms for, 265–269
  - validation phase assays in, 265
- Plasma lipids and lipoproteins
  - candidate genes regulating, 50–51

- dietary and genetic influences on, 50–54  
**Polyethylene glycol (PEG) as continuous marker for fecal collection**, 386–387  
**Polymerase chain reaction (PCR)**  
   amplification, 48  
   defined, 56  
**Popcom, substitutions for**, 163  
**Posters as recruitment strategy**, 81–84  
**Potassium excretion compared with intake to assess dietary compliance**, 382  
**Poultry and meats**  
   HACCP safety and sanitation measures for, 187–188  
   purchasing, 181, 187  
**Power in calculating sample size**, 14, 52–53, 118–119, 391  
**Pregnancy**  
   cessation of menses as first sign of, 110  
   reported to study staff, 120  
   screening of prospective participants for, 120  
**Pregnancy testing**, 120  
**Pregnant women**  
   controlled diet studies on, 120, 122  
   water intake of, 233, 234, 236  
**Principal investigators in controlled diet studies**  
   knowledge about potential conflict of interest of, 73  
   masking techniques and, 200  
   problems in recruitment and implementation addressed by, 72  
   relationship with professional nutrient staff of, 302  
   requests for change in protocol addressed by, 100  
   roles and supervision of, 62, 63, 74, 97, 302  
   salary for, 153  
**Prisoners as participants in controlled diet studies**, 65  
**Product label information**, 21  
**Production sheet for staff workstations**, 265, 273  
**Professional organizations**  
   code of ethics by, 62, 65  
   list of, 193  
**Progesterone levels**  
   serum, 112  
   of women on vegetarian diets, 118  
**Progesterone production**, 111  
**ProNutra Nutrient Analysis System for Metabolic Studies**, 27, 38, 166  
**Prospective cohort studies**, 2, 3  
**Protein**  
   egg, 222  
   inverse relationship of blood pressure level and amount of dietary, 391  
   milk, 222–223  
   sources of, in formula diets, 222  
   soy, 223  
   whey, 218, 223  
**Protein content of food sample**, 358–359  
**Protein status revealed in nitrogen balance studies**, 247–249  
**Protein substitute products for meat**, 199  
**Protein values in databases**, 157  
**Protein-free food recipes**, 215–218  
**Protocol for controlled diet studies**  
   adapted for children, 127, 130–136, 138  
   demographic information for, entering, 21  
   detailed, 375  
   diet assay as part of, 342–346  
   documentation and updates for, 264  
   feasibility of, 7  
   flexibility within, 99  
   fluid intake considerations in designing, 237  
   intensity ranking guide for, 301, 302  
   for multicenter studies, 397–398, 401  
   pilot test of, 97, 149–150  
   procedures that minimize effects of physiological variations in, 376  
   psychological constraints imposed by, 132  
   recording deviations from, 206  
   requests for changes in, 99–100, 102  
   staff meeting for review of, 97  
   staffing based on complexity of, 299, 309, 313–314  
   suitable substitutions within, 328–329  
**Provisional Table on Retention of Nutrients in Food Preparation**, 158  
**Psychosocial factors in selecting participants**, 91–94  
**Publishing results of controlled diet studies**, 320, 322, 397, 398  
**Puddings as unit foods**, 260  
**Puddings in solid formula diets**, 214  
   basic, 215  
   protein-free cornstarch, 216  
   protein-free wheat starch, 215–216  
   solid fat in, 226  
**Q**  
**Quality assurance for study meals**, 72, 399  
**Quality assurance program**, 315, 320, 321  
**Quality control**  
   of assays, 358  
   of chemical analysis, 346, 348–350  
   of formula diets, 230  
   of laboratory, 368–378  
   for multicenter studies, 397  
   for multiple concurrent studies, 315  
**Quality control charts (QC charts)**, 360–361  
   sample, 369–370  
**Quality control checklist for tray contents**, 196, 275  
**Quality control forms**, 265, 274–276  
**Quality control material (QCM)**, 358–360  
**Quality control program for staff performance**, 323–333  
**R**  
**Radio advertising as recruitment strategy**, 81–83  
**Radioactive isotopes**  
   differences between stable isotopes and, 250  
   tracers using, 189–190  
**Radio-opaque pellets (ROP) as intermittent markers**, 386  
**Randomization procedure in assigning participants**, 15–16, 72  
**Recipes**, 270–289  
   calculated in nutrient calculation software, 23, 167–168, 171  
   calculation of, individualized, 214, 220  
   computer applications for printing scaled, 31–33  
   elements of, 270–271  
   evaluated and revised during pilot studies, 149–150  
   for formula diets, 212, 228, 230  
   in permanent study file, 265  
   quality control checks for, 271  
   weights of ingredients in, 272–274  
**Recipes, food**  
   for baked chicken breast, 287–288  
   for banana bread, 282  
   for basic muffin loaf, 285  
   for basic pudding, 215  
   for chocolate drop cookies, 286  
   for East Indian cauliflower, 286–287  
   for ginger thins, 286  
   for Greg's herb butter, 280  
   for Greg's low-sodium vinegar and oil salad dressing, 280–281  
   for lemon baked chicken, 288  
   for lemon cookies, 285–286  
   for Liquid Formula B, 218–219  
   for Liquid Formula C, 220  
   for low-salt Salisbury steak, 287  
   for low-sodium sugar cookies, 281  
   for macaroni and cheese, 288–289  
   for oatmeal cookies, 284–285  
   for pound cake, 282–283  
   for protein-free cookies, 217  
   for protein-free cornstarch pudding, 216  
   for protein-free wheat starch pudding, 215–216  
   for Shuli's low-protein fruit topping, 279–280  
   for sponge cake, 283  
   for sugar cookies, 281–282



- for unit oatmeal cookies, 278
  - for unit muffins, 278–279
  - Recommended Dietary Allowances (RDA)
    - comparing nutrient content of research diet to, 264
    - comparing nutrient intake to, 24, 132, 155
    - difficulty of meeting some, 155–156
  - Recruitment meetings for recruitment and screening, 81–82, 84–85
  - Recruitment of study participants, 76–87, 302
    - budget considerations for, 81, 153
    - of children, 136–137
    - ethical issues in, 64, 68–70
    - for genetic studies, 54–55
    - goal of, 76–77
    - incentives in, 86
    - IRB's role in, 80
    - modifying, 86
    - monitoring, 81–82
    - for multicenter studies, 392
    - pilot studies of, 94, 149–150
    - planning, 80–81
    - revising eligibility criteria based on experience of, 77
    - of special populations, 85–86
    - staffing needs for, 80–81, 302
    - strategies for, 81, 82–85, 161–162
    - time required for, 80
    - weight ranges discussed during, 204–205
    - of women, 85, 119–120
  - Recruitment plan, 77
  - Regression to the mean, 13
  - Regulations for the Protection of Human Subjects (DHHS) (45 CFR 46), 64
  - Reorder points in inventory, 33
  - Research diets. *See* Diet types and Diets, research
  - Restriction fragment length polymorphisms (RFLPs), 48, 56
  - Results of controlled diet studies
    - generalizability of, 77
    - reporting, 74
  - Returnable containers for food eaten off site, 105
  - Riboflavin as marker of dietary compliance, 382
  - Risk factors for disease, 2
    - dietary effects on, 4
  - Run-in period for controlled diet studies, 12
    - for children, longer, 135
    - for multicenter studies, 401
- S**
- Safety monitoring boards
    - advice about abnormal laboratory values of participants from, 69
    - oversight role of, 62, 64–65
  - St Jeor and Bryan diet classification system, 143–144
  - Saliva samples for menstrual phase identification, 112–113
  - Sample collection, 379–389. *See also* Blood collections during controlled diet studies, Fecal collection, and Urine collection
    - from children, 135–137
    - effects of hormonal and reproductive status on, 122
    - of hair and nails, 388
    - reasons for using, 379
    - of saliva, sweat, breast milk, and expired CO<sub>2</sub>, 388
    - security issues in, 298
    - staffing needs for, 303
    - standardizing, 117
    - tracking specimens as beginning with, 375
    - visits of outpatient participants scheduled by, 197
  - Sample size for participants, 6, 10–12, 14–15
    - effects of hormonal variations and menstrual cycles on, 118–119
    - formulas for calculating, 15
    - for heritability estimates, 51–54
    - ways of obtaining sufficient, 391–392
  - Sampling errors, 350
  - Saturated Fat Diet, 172–176
  - Scaling food weights, 24
  - Scientific evidence
    - example of lines of, 5
    - to test diet-disease relationship, 2
  - Scientific rationale of controlled diet studies, 2–9
  - Scrape and wash technique of food consumption, 200
  - Screening of prospective participants in controlled diet studies, 69–70, 77, 87–95
    - of children, 136–137
    - findings of, factored into study orientation and education for compliance, 104
    - first, second, and third stages of, 87, 88
    - food- and diet-related issues during, 92–93
    - for formula diet protocols, 213
    - habitual lifestyle of participants examined during, 91–92
    - for hormonal and reproductive status, 120–122
    - interaction patterns of participants examined during, 92
    - for multicenter studies, 396
    - pilot studies of, 94
    - pool size for, 89, 91
    - staffing needs for, 302
    - staggering, 80
  - strategies for collecting information during, 89
  - study disclosure during, 91
  - visits for, 87–88, 396
  - Seasonal adjustment in controlled diet studies, 17
  - Seasonal effects on nutrients, 148, 337
  - Segregation analyses, 47, 56
  - Selenium studies
    - of effects, 159
    - of metabolism, 252
  - Senior research dietetic technician position description for, 310
  - responsibilities of, 303, 306, 310
  - time analysis for dietary tasks of, 309
  - Serum hormone levels, 112, 119
  - Service, quality, to guarantee participant satisfaction, 330, 332
  - Seven Step Approach to constructing quality control program, 324–327
  - Siblings in genetic studies, 45–46
  - Snacks
    - caloric distribution among, 160
    - for children added to meal plans, 133
    - hunger problems solved by, 204
    - for students, 161
  - Sodium balance
    - affected by menstrual cycle, 116–117
    - affected by sweating, 244
    - variance in, 340
  - Sodium content
    - of bouillon, 213
    - of chewing gum, 208
    - of foods and toothpaste, 164–165, 209
  - Sodium levels as indicator of dietary compliance, 381–382
  - Solute load of formula diets, 219, 221
  - Soy products, 190
    - in formula diets, 222, 223
  - Specimen banking, 377–378
  - Spreadsheet program
    - used for matrix arithmetic and linear or integer programming, 26
    - used to analyze food costs, 33, 39
    - used to generate food production sheets, 30
    - used to generate menus, 33, 37
    - used to generate scaled recipes, 33
    - uses in controlled diet studies, 28
  - Stable isotopes. *See also* individual isotopes
    - compartmental modeling with, 249–250
    - differences between radioactive isotopes and, 250
    - safety issues for, 251
    - uses of, 240, 251–252
  - Staff of controlled diet studies, 299–322
    - access to participant information by, 72

- accommodation of children's needs  
by, 137
- additional support for, 315
- as authors of scientific papers, 74
- budgeting, 152–153
- conflict of interest of, 72–73
- duty schedules for, 270, 271
- ethical obligations to, 72–74
- excluded from participation in  
study, 73
- explanation of study requirements to  
participants by, 69
- handling of biohazardous materials  
by, 73
- hiring and firing, 73
- for inpatient vs outpatient studies,  
298
- labor costs of, 150–151
- morale of, 331
- for multicenter studies, 398
- for multiple dietary treatments, expe-  
rienced, 147
- offices of, 296, 297–298
- orientation of, 98
- part-time, 73, 150
- pilot study duties of, 150
- planning, 151, 299–302, 313–315,  
319
- position descriptions for, 305, 310–  
312, 315, 320
- records of assigned, 147
- for recruiting participants, 80–81
- responsibility for welfare of, 62
- scheduled to meet needs of protocol,  
163–164
- shifts for, 315
- space and equipment as governing  
numbers of, 149
- titles and descriptions of, 303
- training and in-service education of,  
189, 320, 387, 402
- trust between participants and, 99
- workload of, forms for, 265, 270–  
273
- written procedures provided to, 97
- Standard reference materials (SRMs),  
358
- Statistical analysis software uses in con-  
trolled diet studies, 28–29
- Statistics in controlled diet studies, 6,  
10–18, 118–119
- Steroidal contraceptives, 115
- Stool samples. *See* Fecal collection
- Study design for controlled diet studies,  
1–60, 62–63
- adapted for children, 127
- improving, for menstrual cycle con-  
siderations, 118–119
- potential for growth problems in, 134
- to test hypothesis, 5–6
- Subsamples for assays, 347, 354–355
- Substituted foods. *See* Food substitutions  
in controlled diet studies
- Sugars
- relative sweetness of, 223, 225
- types of, 223–224
- Suggestion box for participants, 102
- Summary statistics, 15
- Survey Nutrient Database, 21
- T**
- Take-out meals
- eating techniques for, 204, 205
- food selection for, 146
- forms for participants having, 265,  
276
- packing, in coolers with ice packs,  
146, 197, 328
- packing list of food items in, 99, 197
- participants assembling items for, 151
- requests for, 205
- staff directions for safe storage and  
reheating of, 99
- Telephone recruitment strategies, 81–82
- Television advertising as recruitment  
strategy, 81–83
- Termination from controlled diet studies
- of children, 136
- ethical considerations of, 65, 67,  
69, 71
- of participants refusing provided  
foods, 162, 401
- Test diets, multiple, 17
- Thermic effect of food (TEF), 258, 260
- Time factors in controlled diet studies, 6
- Tobacco, extraneous nutrients in and  
metabolic effects of, 209
- Toothpaste, extraneous nutrients from,  
164–165, 209
- Total error (TE), calculating, 371
- Trace elements, 159
- Trade organizations for food, 191–192
- Trans* fatty acids, assays of, 356
- Transmission disequilibrium tests  
(TDT), 49, 56
- Tray assembly, 196, 323, 328–329
- Tray checks
- critical points for, 328
- to ensure completeness of meal be-  
fore delivery, 105, 196
- to find uneaten food after trays are  
returned, 105
- minimizing clutter on trays for, 147
- quality control checklist for, 196
- Tray delivery, critical points in, 329
- Trial period of controlled diet study, 144
- T-test comparison of test diets, 17
- Twin studies, 2
- challenges of, 52–53
- HDL metabolism examined in, 51
- influence of genetic factors on body  
fat storage and mobilization as  
subject of, 45
- study designs for, 45–46
- zygosity determination in, 55
- Twins
- monozygotic (MZ) vs dizygotic  
(DZ), 45, 51, 53
- registries and national organizations  
for identification and recruitment  
of, 54
- U**
- Ultrasound to determine menstrual  
phase, 113
- Unit foods
- defined, 198, 271
- examples of, 198
- in multicenter studies, 401
- recipes for, 278, 279
- Urine, acidifying effects of exercise on,  
164
- Urine collection
- in balance studies, 246, 248, 249, 252
- challenges in making, 379
- creatinine as marker to ensure com-  
pleteness of, 383–384
- knowing water intake to estimate  
completeness of, 237
- PABA as marker to ensure complete-  
ness of, 245, 381, 383, 384
- procedures for, 382–383
- sources of error in, 245
- in stable isotope experiments, 250
- Urine specimens
- analyzing, 382
- storing, 245
- timed, for free-living participant stud-  
ies, 245
- to track hormone levels, 112
- water intake pattern manipulated for  
timed, 237
- US Department of Agriculture (USDA),  
datasets maintained by, 21–22,  
156–157
- USDA Nutrient Data Base for Standard  
Reference (Release 12) (SR-12),  
21, 156–157
- data for, 160, 336–337
- database files for, 166–167
- development of, 336
- as origin of nutrient values, 336
- portions in, 160
- recipe nutrients analyzed by, 280–  
287
- sample recipes using nutrient content  
calculations from, 271, 289
- selenium content in, 159
- V**
- Validation of diet, prefeeding, 344–345
- Validation queries for database en-  
tries, 24
- Variation
- analytical, 372, 374
- estimates for, 14–15

- normal physiological, 371–377
  - sources of, in laboratory measurements, 369–375
  - total, 373–374
  - Vegetarian diet
    - blood pressure-lowering effect of, 391
    - effect on menstrual cycle of, 118
  - Vending machine feeding systems, 198
  - Vitamin A metabolic balance study, 252
  - Vitamins
    - effects of cooking and handling foods on their, 168
    - extraneous nutrients from, 207
    - in formula diets, 216
    - formulating research diets for content of, 158–159
    - supplements containing, 196, 207
    - variance in foods' content of, 337
- W**
- Washout periods
    - length of, 145
    - purpose of, 12, 144
  - Water
    - allowances for, 232
    - controlling mineral content of, 185, 186, 207–208, 237
    - deionized, 185, 186, 207–208, 222, 237
    - distilled, 222
    - drinking the rinse, 213, 244, 246, 250
    - in extracellular spaces vs plasma, 240
    - intake of, in controlled diet studies, 234–237
    - providing, in controlled diet studies, 236–237
    - typical quantities and sources of intake for, 232–234
  - Water balance, regulating, 219, 221
  - Weighed diets, 143, 307, 309
  - Weight changes during controlled diet studies, 204–205, 255, 260–261
  - Weight maintenance during controlled diet studies
    - dietary techniques for, 260
    - for multicenter studies, 396, 401
  - Weight records of participants, documenting, 265
  - Weights of common food serving sizes, 182–184
  - Women
    - concerns in controlled diet studies of, 122
    - design issues for studies enrolling, 117–119
    - hormonal status of, 109–116, 119–120
    - menstrual cycle of. *See* Menstrual cycle
    - reproductive states in, 110, 120
  - Women as participants in controlled diet studies, 6, 109–125
    - exclusion of, 109
    - NIH mandate for inclusion of, 109
    - recruiting, 85, 119–120
  - Word processor uses in controlled diet studies, 27–28, 32, 36
  - World Health Organization (WHO) factorial method to estimate energy needs, 258
  - World Wide Web (WWW or Web), 34–35
- Z**
- Zinc and copper balance study (NASA), 391
  - Zinc, copper, and iron balance study, 246–248
  - Zinc kinetics, 240
  - Zygosity determination in twin studies, 55