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Content Outline for a Curriculum in Research Education for General Academic Fellowship Programs

Ambulatory Pediatric Association Research Committee
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RATIONALE

The Ambulatory Pediatric Association (APA) Research Committee has undertaken to develop a content outline for a curriculum in research education at the fellowship level. The development of such an outline was part of the strategic plan defined by the APA Board of Directors in the fall of 1999. The APA Research Committee sponsored a workshop regarding the development of a curriculum in research education at the Pediatric Academic Societies meeting in May 2002. This content outline is an outcome of that workshop.

The need for such a curriculum is based on the lack of guidelines for the General Academic Pediatric (GAP) fellowship programs. Since there is no ACGME board certification for GAP fellowships, no existing requirements for research education exist. The Research Committee believes a content outline for a curriculum in research education will be useful to fellowship directors in evaluating their programs and planning for program changes. The content outline may also assist fellowship applicants in choosing fellowship programs.

This content outline is also in response to the American Academy of Pediatrics (AAP) Policy Statement, written by the AAP Committee on Pediatric Research, published in Pediatrics in June 2001 and entitled "Promoting Education, Mentorship, and Support for Pediatric Research". Specifically, this content outline responds to the section of that policy statement on "Research Training in Pediatric Fellowship Programs", and conforms with the recommendations: "Fellowship programs should include advanced formal course work in research methodology that covers the widest possible spectrum of child health research."

and

"A research methodology curriculum should be developed that will outline the minimal core knowledge and skills expected of all child health researchers...."

Furthermore, we anticipate that this content outline will be helpful to other organizations promoting research education. Specifically, the leadership of the Society for Developmental and Behavioral Pediatrics has expressed an interest in co-sponsoring these guidelines for fellowships in Developmental-Behavioral Pediatrics

OVERARCHING PRINCIPLES

There are a number of overarching principles concerning the content outline which is listed in detailed format below.

- Level of competency to be achieved by trainees

Fellowship programs may choose to offer research education that achieves a minimum level of competency for fellows, or offer more advanced training. For example, goals for minimum competency may include:

- Be familiar with basic research theories and principles and be able to use this knowledge for critical appraisal of literature and/or ongoing research
- Be able to design clinical and population-based research with guidance

Goals for advanced competency may include:

- Be able to use statistical databases to collect and analyze data
- Be able to design and perform clinical research independently
- Be able to design and perform clinical research in a supervisory capacity

In addition there may be different levels of knowledge and skills for fellowships in different fields (e.g., Fellowships in General Academic Pediatrics may require only introductory knowledge and limited skills in selected techniques of biomolecular research as opposed to some pediatric subspecialties which may expect far greater knowledge and skill acquisition in biomolecular research techniques)

- Quality and quantity of educational experience

Fellowship research education may be accomplished through a variety of methods. Some fellowships may offer an MPH or other masters program for their fellows, others a certificate program, and others course work that does not lead to a degree or certificate. It is expected that 150 hours of formal instructional time during the fellowship would be the minimum allocation of fellow experience to meet minimal core knowledge and skills in child health research. It is also likely that certain parts of the curriculum, such as the section of "Publishing and Presenting Research", and the use of computer technology, may be accomplished through mentoring and practical experience without formal didactic instruction.

- Mentorship

Mentorship by faculty with extensive research experience is critical to any fellowship program proposing to offer training in child health research. Without such mentorship, course work will be of limited success in promoting skill acquisition by the trainee. As stated in the AAP Policy Statement on pediatric research education: "Programs should assign all fellows to work with experienced faculty research preceptors."

- Practical Experience in Research

Knowledge and skills acquired in didactic instruction needs to be applied by the fellow to the actual conduct of research. In addition to time allocated to course work in research education, fellows should be assigned time to perform research and to meet with research preceptors on a regular basis to review the progress of their research and obtain guidance in the design, implementation and analysis of the research project. It is appropriate for fellowships to have specific objectives for the fellow to accomplish by the end of the fellowship training. At a minimum, fellowships should expect the following products by the end of fellowship training:

- Preparation of an IRB proposal
- Design and implementation of a component of an ongoing research study or research on secondary data
- Abstract for presentation at regional/national meetings
- Presentation at regional/national meetings

Some fellowships may want to set more advanced minimal objectives for their fellows to accomplish by the end of fellowship training:

- Design and implementation of an independent research study
- Paper submitted/accepted for publication
- Preparation of an application for grant funding

CONTENT OUTLINE

I. Research Design

- A. Formulating a research question
 - 1. Review of the literature
 - 2. Determining relevance and unique contribution to literature
 - 3. Establishing feasibility
 - 4. Selecting appropriate research methodology
- B. Hypotheses
 - 1. Characteristics:
 - a. Specific vs. vague
 - b. Single vs. multiple
 - c. A priori vs. post-hoc
 - d. Null, alternative
- C. Sampling
 - 1. Specifying a study population
 - a. Population vs. sample
 - b. Inclusion and exclusion criteria
 - c. Population-based vs. clinic-based samples
 - 2. Sampling strategies
 - a. Convenience and consecutive samples
 - b. Random samples: simple, stratified
 - c. Systematic samples
 - 3. Recruitment of subjects
 - a. Representative sample
 - b. Recruitment strategies
 - c. Estimating non-response and dropout rates
 - 4. Implications for generalizability of findings
- D. Measurement
 - 1. Types of variables
 - a. Nominal and dichotomous
 - b. Ordinal
 - c. Continuous, discrete
 - 2. Deciding what to measure
 - a. Baseline descriptive variables and risk factors
 - b. Outcome variables
 - i. Developing clear criteria for definition and measurement of each variable
 - ii. Clinical outcome vs. intermediate or surrogate variables
 - c. Mediating variables
 - d. Covariates
 - e. Avoiding collecting unnecessary data
 - 3. Reliability (precision)
 - a. Methods of assessing reliability
 - i. Test-retest
 - ii. Inter-rater
 - iii. Internal consistency
 - b. Methods of enhancing reliability: decreasing random error
 - 4. Minimizing bias
 - a. Sources of systematic error or bias: observer bias, subject biases
 - b. Enhancing accuracy: decreasing systematic error
 - i. Blinding to prevent co-interventions and ascertainment bias
 - ii. Making unobtrusive measurements
 - 5. Validity
 - a. Content and sampling validity
 - b. Construct validity
 - c. Criterion-related validity: concurrent, predictive
 - d. Face validity
 - 6. Development and use of questionnaires

- a. generating a list of variables
 - b. Open-ended vs. closed-ended questions
 - c. Responses that are mutually exclusive and cover full range of possible answers
 - d. Formatting
 - e. Wording: clarity, neutrality, non-leading, reading level
 - f. Time frame of questions
 - g. Avoiding complex questions and unwarranted assumptions
 - h. Scales and scores to measure concepts
 - i. Using or modifying existing measures
 - j. Drafting, testing and revising questionnaires
 - k. Validation of questionnaires
 - l. Interviewer-administered and self-administered questionnaires
- E. Error, sample size and power
- 1. Type I, Type II
 - 2. alpha, beta, power
 - 3. p values
 - 4. effect size
 - 5. estimating power and sample size
 - 6. Statistical versus clinical significance
- F. Randomized controlled trials
- 1. Randomizing
 - a. Ensuring honest randomization
 - b. Computer-generated lists of random numbers and how to use them
 - c. Use of block randomization and stratified blocked randomization
 - d. Randomization of matched pairs
 - e. Group or cluster randomization
 - 2. Use of placebo or comparison treatments and choice of controls
 - 3. Standardization of treatments
 - 4. Maximizing follow-up and adherence
 - 5. Adverse effects
 - 6. Monitoring a clinical trial
 - 7. Other designs for clinical trials
 - a. Factorial designs
 - b. Time-series designs
 - c. Cross-over designs
 - 8. Stages (phases) in testing new therapies (FDA)
- G. Observational studies
- 1. Cohort studies
 - a. Types
 - i. Prospective
 - ii. Retrospective
 - iii. Nested case-control, nested case-cohort
 - iv. Double cohorts
 - b. Issues: confounding variables; loss to follow-up, blinding
 - c. Strengths and weaknesses of each type
 - d. Relative risk and excess risk
 - 2. Case-control studies
 - a. Efficiency for rare outcomes
 - b. Usefulness in generating hypotheses
 - c. Sampling bias and methods of controlling for it
 - d. Differential recall bias and ascertainment bias and methods of controlling for it
 - e. Odds ratios to estimate relative risk
 - 3. Cross-sectional studies
 - a. Strengths and weaknesses
 - b. Relative prevalence and excess prevalence
 - 4. Case series
- H. Causality and observational studies
- 1. Spurious associations due to chance
 - 2. Bias

3. Confounding
4. Direction of causality
5. Strategies to enhance causal inferences
 - a. Design strategies
 - i. Specification or exclusionary criteria
 - ii. Matching and overmatching; stratification
 - b. Analysis strategies
 - i. Stratification
 - ii. Statistical multivariate adjustment
6. Strength of evidence for causality
 - a. Temporality: cause precedes effect
 - b. Strength or effect size: bias is less likely to cause large effects
 - c. Dose-response
 - d. Biologic plausibility (lack of biological plausibility may be due to limits of medical knowledge)
 - e. Reversibility: reduction in exposure leads to lower rates of disease
 - f. Specificity: one cause leads to one effect (often not true for chronic diseases)
 - g. Consistency: same results over multiples studies
- I. Studies of diagnostic or screening tests (also see Clinical Epidemiology)
 1. Spectrum of disease severity
 2. Variation of test results based on raters or interpreters or based on clinical setting
 3. Intra-observer and inter-observer variability
 4. Studies of accuracy
 - a. Cross-sectional or cohort designs
 - b. The "gold" or reference standard
 - c. Analysis: sensitivity, specificity, positive predictive value, negative predictive value, likelihood ratios, receiver operating characteristic curves
 5. Studies of effect of clinical decision-making and patient outcomes
 - a. Observational studies vs. clinical trials
 6. Studies of cost-effectiveness and feasibility
- J. Implementation issues
 1. Pilot-testing
 2. Quality control (e.g., training and certification, reliability of measurements, blinding, missing data, periodic review, supervision)
 3. Protocol revisions
- K. Technology
 1. Database design
 2. Minimizing error in data entry (e.g., double entry) and error checking and data cleaning
 3. Database software

II. **Clinical Epidemiology And Evidence-Based Medicine**

- A. Incidence and Prevalence
 1. Definition and use
 2. Relationship of incidence, prevalence and duration of disease
 3. Bias in prevalence studies (case-oriented rather than cohort-oriented) due to early deaths and cures and selection of more severe cases
- B. Risk
 1. Risk difference or attributable risk
 2. Relative risk
 3. Odds ratios
- C. Prevention
 1. Levels of disease: no disease, asymptomatic disease, clinical course, permanent disability and mortality
 2. Levels of prevention
 - a. Primary prevention

- b. Secondary prevention and screening
 - c. Tertiary prevention
- D. Diagnosis and Screening
 1. Test and treatment thresholds in the diagnostic process
 2. Accuracy of a test result
 - a. Concepts of true positive, false positive, false negative, true negative
 - b. Concept of gold or reference standard
 - c. Problem of lack of information on negative tests or on test results in the non-diseased
 - d. Problem of lack of objective standards for disease
 3. Sensitivity and specificity
 - a. Use of sensitive test
 - b. Use of specific test
 - c. ROC curve and trade-offs between sensitivity and specificity
 - d. Spectrum of patients
 - e. Bias due to lack of independence of diagnosis and test results in determining sensitivity and specificity
 - f. 95% confidence intervals for sensitivity and specificity
 4. Positive and Negative Predictive Value
 - a. Effect of prevalence or prior probability
 5. Likelihood ratios
 6. Principles of screening
 - a. Burden of suffering
 - b. Does early diagnosis lead to improved survival or quality of life?
 - c. Properties of a good test:
 - d. Sensitivity and specificity
 - e. Simplicity, low cost and safety
 - f. Acceptability
 - g. Impact of prevalence and concept of screening higher risk populations
 - h. Issues of labeling and risk of false positive screening test
 - i. Bias: Lead time and length time bias; compliance bias
 7. Evidence-Based Medicine: Evaluating Medical Literature and Applying the Results of Studies of Diagnostic Tests
 - a. Validity
 - i. Was there an independent, blind comparison with a reference standard?
 - ii. Did the patient sample include an appropriate spectrum of patients to whom the diagnostic test will be applied in clinical practice?
 - iii. Was the reference standard applied regardless of the diagnostic test result?
 - iv. Were the methods for performing the test described in sufficient detail to permit replication?
 - b. Strength and Importance of Results
 - i. Sensitivity, specificity and predictive values
 - ii. Likelihood ratios
 - c. Application to Clinical Practice
 - i. Is the diagnostic test available, affordable, accurate and precise in the present clinical setting?
 - ii. Are the results applicable to the patient being treated and can we generate a clinically sensible estimate of the patient's pre-test probability?
 - iii. Will the results change the management of the patient being treated and will the patient be better off as a result of the test?
- E. Prognosis
 1. Definition of clinical course, natural history of disease, zero time
 2. Inception cohort vs. survival cohort
 3. Outcomes
 - a. Clinical vs. biologic outcomes
 - b. Quality of life and functional status
 4. Prognostic factors vs. risk factors

- a. Demographic
 - b. Disease-specific
 - c. Co-morbid
- 5. Prediction rules
- 6. Prognosis defined by rates
 - a. 5- or 10-year survival
 - b. Case fatality
 - c. Disease-specific mortality
 - d. Response
 - e. Remission
 - f. Recurrence
- 7. Survival analysis and time-to-event analysis
- 8. Prognostic studies
 - a. Derivation set: What factors predict patient outcomes?
 - b. Validation set: Do these prognostic factors predict patient outcomes accurately?
- 9. Evidence-Based Medicine: Evaluating Medical Literature and Applying the Results of Studies of Prognosis
 - a. Validity
 - i. Was an "inception cohort" assembled?
 - ii. Was patient follow-up sufficiently long and complete?
 - iii. Were objective outcome criteria applied in a "blind" fashion?
 - iv. Was there adjustment for important prognostic factors?
 - b. Strength and Importance of Results
 - i. How likely are the outcomes over time? (e.g., 1-, 5-, 10-year survival rates, median survival, survival curves)
 - ii. How precise are the estimates of prognosis? (e.g., 95% confidence intervals)
 - c. Application to Clinical Practice
 - i. Were the study patients similar to the patient being treated?
 - ii. Will the results lead directly to selecting therapy?
 - iii. Are the results useful for counseling patients?
- F. Therapy
 - 1. Evidence-Based Medicine: Evaluating Medical Literature and Applying the Results of Studies of Therapy
 - a. Validity
 - i. Was the assignment of patients to treatment (experimental and placebo or comparison) randomized?
 - ii. Were all patients who entered the trial accounted for and attributed at its conclusion?
 - iii. Were patients analyzed in the groups to which they were randomized (intention to treat analysis)?
 - iv. Were patients, clinicians and study personnel kept "blind" to treatment received?
 - v. Were the groups similar at the start of the trial?
 - vi. Aside from the experimental intervention were the groups treated equally?
 - b. Strength and Importance of Results
 - i. How large is the treatment effect?
 - Relative Risk Reduction
 - Absolute Risk Reduction
 - Number Needed to Treat
 - ii. How precise was the estimate of the treatment effect (e.g. 95% confidence intervals)?
 - c. Application to Clinical Practice
 - d. Were the study patients similar to the patient to be treated?
 - e. Were all clinically important outcomes considered?
 - f. Are the likely treatment benefits worth the potential harm and costs?
- G. Harm
 - 1. Types of studies of harm:

- a. Cohort studies
 - b. Case-control studies
 - c. Case series
 - d. Relative strength of inference in observational studies
2. Evidence-Based Medicine: Evaluating Medical Literature and Applying the Results of Studies of Harm
- a. Validity
 - i. Except for the exposure under study, were the compared groups similar to each other in all known determinants of the outcome?
 - ii. Were differences adjusted for in the analysis?
 - iii. If a case-control study, were exposed patients equally likely to be identified in both groups?
 - iv. Were the outcomes and exposures measured in the same ways in both groups?
 - v. Was follow-up of patients sufficiently long and complete?
 - vi. Is the temporal relationship correct?
 - vii. Is there a dose-response gradient?
 - b. Strength and Importance of Results
 - i. How strong is the association between exposure and outcome?
 - Relative risk in cohort studies
 - Odds ratios in case-control studies
 - ii. How precise is the estimate of risk (e.g., 95% confidence intervals)?
 - c. Application to Clinical Practice
 - i. Were the study patients similar to the patient to be managed?
 - ii. What is the magnitude of risk?
 - Absolute risk increase
 - Number needed to harm
 - iii. Should an attempt be made to stop the exposure?
- H. Additional and Advanced Topics in Evidence-Based Medicine
- 1. Systematic reviews and Meta-analyses
 - 2. Practice guidelines
 - 3. Decision analysis
 - 4. Economic analysis

III. Special Topics in Research Design

- A. **Qualitative research**
 - 1. In progress: David Grossman, MD, MPH, University of Washington School of Medicine
- B. **Outcomes research and Health Services Research**
 - 1. In progress: Lynn M. Olson, Ph.D, Co-Director of AAP Department of Practice and Research
- C. **Use of secondary databases**

Prepared by Michael Weitzman, MD, Executive Director of AAP Center for Child Health Research and University of Rochester School of Medicine

 - 1. Knowledge of the major existing large datasets:
 - a. Federal
 - i. Cross-sectional: the National Health Interview Survey (NHIS), the National Health and Nutrition Examination Survey (NHANES); the National Ambulatory Medical Care Survey (NAMCS) and the National Hospital Ambulatory Medical Care Survey (NHAMCS); the Medical Economic Panel Survey (MEPS); the Youth Risk Behavior Survey (YRBS); and many others.
 - ii. Longitudinal: the National Longitudinal Survey of Youth (NLSY); the National Maternal-Infant Health Survey (NMIHS); Adolescent Health (ADD Health); the Early Childhood Longitudinal Educational Survey (ECLES)

- iii. Understand that these datasets may be used to answer clinical questions (e.g. do children with iron deficiency score lower on tests of intelligence than children without iron deficiency); epidemiologic questions such as the prevalence and distribution of elevated lead levels, iron deficiency, asthma, and obesity; and policy questions such as how does un-insurance or underinsurance influence utilization of services.
 - iv. Major publications resulting from these datasets in the past 25 years.
 - v. Major child health, development and behavior variables available on each
 - vi. How to obtain datasets and lists of variables
 - vii. SUDAAN software to convert sample to be nationally representative
 - viii. Some programs may consider encouraging all or selected fellows to conduct studies using these datasets:
 - Advantages- data exist, precluding need for IRB approval, collecting and entering data; data often is nationally representative
 - Disadvantages- fellow does not have to design instruments and collect and enter data, or go through process of obtaining IRB approval; variables not always "perfect" for the questions fellow is trying to answer
 - b. Administrative datasets
 - i. Medicaid claims data
 - ii. Private insurance data
 - iii. Health plan data
 - iv. Hospital or clinic administrative data
- D. **Basic knowledge of biomolecular research**
1. In progress: Patricia Ramsay, MD, Ph.D, Associate Director of Neonatology, Driscoll Children's Hospital

IV. **Statistical Analyses**

- A. Basic Statistical analyses
 1. Populations and samples
 2. Types of data
 - a. Discrete vs. continuous
 - b. Nominal, ordinal, interval and ratio data
 3. Frequency distributions
 - a. Graphing data: histograms and bar charts, stem and leaf plots
 - b. Percentiles and percentile ranks
 4. Measures of central tendency and dispersion and when to use them
 - a. Arithmetic mean, median, mode
 - b. Range and interquartile range
 - c. Variance and standard deviation
 - d. Skewness and kurtosis
 5. Probability
 - a. Central limit theorem
 - b. Z scores or standard scores
 - c. Basic probability theory
 - d. Probability and the normal distribution
 - e. Probability and the binomial distribution
 - f. Distribution of sample means
 - g. Standard error of the mean
 6. Statistical inference
 - a. Convention of hypothesis testing: null and alternative
 - b. The level of statistical significance, or alpha level

- c. Type I and Type II errors, alpha and beta probabilities
- d. Power and the relationship between beta and N; effect size and sample size estimation
- e. Two tails vs. one tail
- f. Statistical significance vs. clinical importance
- 7. Analysis of Variance: Comparing groups
 - a. t-test
 - b. ANOVA
 - i. One-way ANOVA and the F distribution
 - ii. Multiple comparisons: Tukey's HSD, Scheffé, Bonferroni, Newman-Keuls, Dunnett's
 - iii. Factorial ANOVA
- 8. Repeated Measures among groups
 - a. Paired t-test
 - b. Repeated measures ANOVA
 - i. Reliability: intraclass correlation coefficient
- 9. Simple regression and correlation
 - a. Pearson, Spearman, Point-biserial and Phi correlation coefficients
 - b. Regression equations
 - c. Relationship between correlation and regression
- 10. Tests of categorical frequencies and proportions
 - a. Chi-square test for goodness of fit
 - b. Chi-square test for independence
 - c. Subdividing chi-square contingency tables
 - d. McNemar Chi-square test for paired or matched data
 - e. Mantel-Haenszel test for factors
 - f. Binomial distribution, binomial test, and Fisher's exact test
 - g. Reliability: kappa and weighted kappa
- 11. Non-parametric tests for ordinal data
 - a. Mann-Whitney U-test
 - b. Wilcoxon signed-ranks test
 - c. Kruskal-Wallis test
- B. Advanced Statistical analyses
 - 1. Multiple linear regression
 - a. Partial and semipartial correlations
 - b. b_s and β_s
 - c. Stepwise and hierarchical stepwise regression
 - d. Interactions
 - e. Dummy coding
 - f. Problems:
 - i. Outliers
 - ii. Multicollinearity
 - iii. Too many variables: ratio of data to variables, percent change in R^2
 - 2. Logistic regression
 - a. Adjusted odds ratios
 - 3. Survival Analysis
 - b. Ways of summarizing and presenting survival data
 - c. Life table analysis
 - d. Kaplan-Meier analysis
 - e. Mantel-Cox log-rank test
 - f. Cox proportional hazards model
 - 3. MANOVA-multivariate analysis of variance
 - 4. ANCOVA-analysis of covariance
 - 5. Factor analysis
 - 6. Structural equations and path analysis
- C. Technology
 - 1. Using statistical packages, e.g. SPSS, SAS, STATA, Epi Info, SUDAAN

V. Responsible Conduct Of Research

- A. Data acquisition, management, sharing, and ownership
 - 1. defining what constitutes data
 - 2. keeping data paper or electronic files
 - 3. data privacy and confidentiality
 - 4. data selection, retention, sharing, ownership, and analysis
 - 5. data as legal documents and intellectual property, including copyright laws
- B. Mentor/trainee responsibilities
 - 1. the role and responsibilities of a mentor
 - 2. conflicts between mentor and trainee
 - 3. collaboration and competition
 - 4. selection of a mentor
 - 5. avoiding abuse of the mentor/trainee relationship
- C. Publication practices and responsible authorship
 - 1. collaborative work and assigning appropriate credit
 - 2. acknowledgments
 - 3. appropriate citations
 - 4. repetitive publications
 - 5. fragmentary publication
 - 6. sufficient description of methods
 - 7. corrections and retractions
 - 8. conventions for deciding upon authors
 - 9. author responsibilities
- D. Peer review
 - 1. the definition of peer review
 - 2. impartiality
 - 3. how peer review works
 - 4. editorial boards and ad hoc reviewers
 - 5. responsibilities of the reviewers
 - 6. privileged information and confidentiality
 - 7. publication bias
- E. Collaborative science
 - 1. setting ground rules early in the collaboration
 - 2. avoiding authorship disputes
 - 3. the sharing of materials and information with internal and external collaborating scientists
 - 4. Issues involved in multi-site and community-based research
- F. Human subjects
 - 1. the definition of human subjects research
 - 2. ethical principles for conducting human subjects research (underlying premises: the proposed research is necessary for improvements in health and welfare, and research is a privilege not a right)
 - a. *respect for persons*: individuals should be treated as autonomous agents, and persons with diminished autonomy are entitled to protection
 - b. *beneficence*: do no harm, and maximize possible benefits and minimize possible harm
 - c. *justice*: selection of research subjects should not be biased, either in exploiting populations that may be easily available or compromised, or be excluding patients who may benefit
 - 3. informed consent and preparation of consent forms
 - 4. consent and assent
 - 5. confidentiality and privacy of data and patient records
 - 6. risks and benefits
 - 7. special issues concerning randomized placebo-controlled and blinded trials
 - 8. deception in social science research
 - 9. preparation of a research protocol for institutional review boards

10. institutional review boards
11. adherence to study protocol
12. proper conduct of the study
13. special protections for targeted populations, e.g., children and minorities.
- G. Research involving animals (if indicated)
 1. definition of research involving animals
 2. ethical principles for conducting research on animals
 3. Federal regulations governing animal research
 4. institutional animal care and use committees
 5. treatment of animals
- H. Research misconduct
 1. fabrication, falsification, and plagiarism
 2. error vs. intentional misconduct; institutional misconduct policies; identifying misconduct
 3. procedures for reporting misconduct
 4. protection of whistleblowers
 5. outcomes of investigations, including institutional and Federal actions
- I. Conflict of interest and commitment
 1. definition of conflicts of interest and how to handle conflicts of interest.
 2. conflicts associated with collaborators
 3. conflicts associated with publication
 4. financial conflicts
 5. obligations to other constituencies, and other types of conflicts.
- J. Oversight of research staff

VI. **Publishing And Presenting Research**

- A. Uniform and specific requirements for manuscripts submitted to medical journals
- B. How to write up the sections of a paper for publication:
 1. Title and abstract
 2. Introduction
 3. Methods
 4. Results
 - a. Numerical precision
 - b. Summarizing data
 - c. Reporting estimates and confidence intervals and p values
 - d. Reporting results of statistical analyses
 5. Tables
 6. Figures
 7. Discussion
 8. References
 9. Authors and acknowledgements
- C. Choosing a journal and responding to reviewers' comments
- D. Presentations
 1. Posters
 2. Oral presentations
 3. Communicating results to lay audiences and the media
- E. Technology
 1. Remedial and advanced word processing (e.g., Word) as necessary
 2. Remedial and advanced presentation software (e.g., Powerpoint) as necessary
- F. Suggested references
 1. Browner WS. Publishing and Presenting Clinical Research. Lippincott, Williams &Wilkins, 1999.
 2. Lang TA, and Secic M. How to Report Statistics in Medicine: Annotated Guidelines for Authors, Editors, and Reviewers. American College of Physicians, 1997.

VII. Funding and Research Support

- G. Public and private funding sources
- H. Identifying funding priorities (e.g., NIH Guide, RFAs, RFPs, Program Announcements, etc.)
- I. Preparation of a grant application
- J. Budget calculation; direct and indirect costs
- K. Grant management

RESOURCES

Research Design

1. Hulley SB, Cummings SR, Browner WS, et al. *Designing Clinical Research*, 2nd ed. Philadelphia, Lippincott Williams and Wilkins, 2001
2. DeAngelis, C. *An Introduction to Clinical Research*. New York, Oxford University Press, 1990
3. Fowler, Jr. FF. *Survey Research Methods*, 2nd ed. Newbury Park, Sage Publications, 1993

Clinical Epidemiology and Evidence-Based Medicine

1. Fletcher RH, Fletcher SW, Wagner EH. *Clinical Epidemiology: The Essentials*. 3rd ed. Philadelphia, Lippincott Williams and Wilkins, 1996
2. Sackett DL, Haynes RB, Tugwell P, Guyatt GH. *Clinical Epidemiology: A Basic Science for Clinical Medicine*, 2nd ed. Philadelphia, Lippincott Williams and Wilkins, 1991 3. Guyatt GH, Rennie D (Eds). *Users' Guides to the Medical Literature*. Chicago, AMA Press, 2002
3. Sackett DL, Strauss SE, Richardson WS, et al. *Evidence-Based Medicine: How to Practice and Teach EBM*. 2nd ed. Edinburgh, Churchill Livingstone, 2000 5. Friedland DJ, Go AS, Davoren JB, et al. *Evidence-Based Medicine: A Framework for Clinical Practice*. Stamford, Appleton and Lange, 1998
4. Riegelman RK. *Studying a Study and Testing a Test*, 4th ed. Philadelphia, Lippincott Williams and Wilkins, 2000

Statistical Analyses

1. Norman JR, Steiner DL. *Biostatistics: The Bare Essentials*. Hamilton, B.C. Decker, Inc., 2000.
2. Glantz SA. *Primer of Biostatistics*, 5th ed. McGraw-Hill/Appleton and Lange, 2001
3. Gravetter FJ, Wallnau LB. *Statistics for the Behavioral Sciences*, 5th ed.. Wadsworth Thomson Learning, 2000
4. Munro BH. *Statistical Methods for Health Care Research*, 3rd ed. Philadelphia, Lippincott Williams and Wilkins, 1997
5. Fleiss JL. *Statistical Methods for Rates and Proportions*, 2nd ed. New York, John Wiley and Sons, 1981
6. Katz MH. *Multivariable Analysis: A Practical Guide for Clinicians*. Cambridge, Cambridge University Press, 1999
7. Cohen J, Cohen C, et al. *Applied Multiple Regression/Correlation Analysis for the Behavioral Sciences*, 3rd ed. Lawrence Erlbaum Associates, 2002
8. Glantz SA, Slinker BK. *Primer of Applied Regression and Analysis of Variance*, 2nd ed. McGraw-Hill/Appleton and Lange, 2000

Publishing and Presenting Research

1. Browner WS. *Publishing and Presenting Clinical Research*. Philadelphia, Lippincott Williams and Wilkins, 1999
2. Lan TA, Secic M. *How to Report Statistics in Medicine: Annotated Guidelines for Authors, Editors, and Reviewers*. American College of Physicians, 1997