

A Checklist for Assessing/Verifying the Integration of the Design in PHS Health Services Research Proposals

by Michael Dennis

Chestnut Health Systems,

720 West Chestnut, Bloomington, IL. 61701

(This document may be duplicated and distributed without charge
as long as the original authorship is acknowledge)

(last revised 1/1999)

Because of space limitations, no proposal can cover everything. The key to a successful proposal is to have a very focused research problem and design. This is often difficult in Health Services and Clinical Research because the problems, populations, context, interventions, outcomes and analyses are often extremely complicated. Given the limited space and need to cover a lot of specific details, this checklist has what? Everything that focuses on or supports it should be given priority. In general, most people need to focus less on their own prior work (which is often of only passing relevance), and focus more on defining exactly what they are proposing at the current time. This list has been prepared to identify a key checklist of issues that either should be addressed in the proposal or issues that have intentionally been left out after consideration.

The list is broken into two major sections. The first deals with cross-cutting issues that need to be addressed conceptually somewhere in the proposal. The second proceeds section-by-section through the PHS proposal and reviews issues that should be addressed in each section. These lists are based on the experience of many reviewers as well as grant review publications available from the NIH office of peer review (www.nih.gov). The specific comments, however, are my opinions and interpretations and do not represent official government positions. If you have comments or suggestions, please feel free them to direct them to me at mdennis@chestnut.org or call me at 309-827-6026.

Michael Dennis, Ph.D.
Senior Research Psychologist
Chestnut Health Systems

Part 1. Cross-Cutting Issues

A. Conceptual Issues

Have you...

- ___ Identified a core problem?
- ___ Identified your next substantive step or intervention?
- ___ Identified the major limitations of prior research and which of these you will try to address?
- ___ Developed a preliminary set of hypotheses and a design for testing them, and identified issues you will need to address (e.g., threats to internal, statistical, construct, and/or external validity)? (Do this before drafting background or preliminary studies!)
- ___ Established the generalizability of the proposed study to the field (particularly important when proposing a very select population or study that requires a lot of resources)?

B. Methodological Issues

Have you...

- ___ Identified the core competencies that will be required to do the proposed research in terms of population, service system, proposed interventions, measurement, statistical analysis and publication/dissemination?
- ___ Identified how you will demonstrate core competencies through the training/experience of the core team, consultants, or through the proposal itself?
- ___ Compared what you are proposing to the state of the art for similar studies? (Documenting the norms if there is an expected problem or low response rate, or if it is an emerging area/method).
- ___ Established the feasibility and promise of any new interventions or methods? (Where possible, provide backup or alternatives in case they fail.)
- ___ Proposed a proportionate step (e.g., descriptive/feasibility study, pilot study, efficacy, effectiveness) if it is a new method or intervention?
- ___ Justified the use of any heterogeneous samples, uncontrolled/usual care conditions, or other sources of variability and then proposed appropriate methods for dealing with them?
- ___ Established an awareness of the limits of the proposed data or method (e.g., records data), proposed methods for limiting or addressing them, and discussed why the need to answer the questions in this way (or time) outweighs the remaining problems.
- ___ Focused on why your approach makes sense and avoided unnecessary attacks on other methods (e.g., statistical vs. experimental; logistic vs. regular regression) and/or proposed multiple methods/measures/definitions where feasible to address multiple perspectives on a particular issue?
- ___ Focused your design and write-up on the core problem? (Underlying complicated designs and sidebar studies often backfire because they cannot be covered in sufficient detail given the limited space and raise many questions.)

C. Logistical/Approval Issues

Have you...

- ___ Talked over the core concept with NIH staff to determine the most appropriate institute branch, and programs?
- ___ Reviewed the program's expectations for the average proposal size, growth, and duration (and removed anything that exceeds them)?
- ___ Gotten a formal letter of approval from the branch if the budget is over \$500,000?
- ___ Established possession and/or your right to use the data (i.e. obtained letters from agencies or other investigators whose data you propose to use)?
- ___ Reviewed general PHS guidelines for grant submission, particularly requirements related to human subject review, inclusion of women, minorities and special populations?
- ___ Established the level of staff ability, commitment and availability (i.e. at least one senior person with experience in the field of the funder.)?

D. Miscellaneous

- It is acceptable for an investigator to be from outside the field of the funder (e.g, a primary care physician studying alcohol issues), but the proposal should demonstrate that the person is familiar with the field and the grant staff should include someone who has a record of publishing or presenting in relevant forums (e.g., Health Service Research Association conferences or clinical journals in the field)
- It is acceptable to propose descriptive studies if the need for information is the next logical step.
- Similarly, studies of natural change are acceptable and may be the most appropriate method of evaluation (e.g, studies of new DUI laws, changes in drinking age, changes in medicaid benefit caps for substance abuse treatment.)
- Statistical modeling is often appropriate, but quickly becomes impractical for complicated problems with small sample sizes or weak measures. The feasibility of a proposed analytic method still needs to be established and its limitations fully discussed.
- Even when experimental methods are proposed, they can fail – there should be adequate discussion of procedures to ensure compliance and to analyze the data if contamination or other problems arise.

Part 2. General Issues Research Design

A. Abstract and Aims

Did you...

- Summarize the problem?
- Have a maximum of two or three aims?
- Design the aims to be readily translated into your testable hypotheses?
- Show or discuss your analytic or theoretical model?
- Summarize the design, population, data sources and proposed analyses?
- Identify the “next step” you will be taking in the proposed research?
- Identify the “methodological problems” you will be addressing?
- Summarize your application’s strengths in the each of the review criteria areas listed in the program announcement (PA) or request for applications (RFA)? (For most NIH health services research grants this will include: relevance, significance, innovation, integration, approach, investigator, and environment.)
- Keep the length to no more than 1 1/4th page? Is there an actual word limit?

B. Background

Did you...

- Include a section explaining the conceptual or theoretical model upon which the work will be based (including a diagram or picture where appropriate)?
- Review literature and/or information estimating the size of the problem?
- Review literature and/or information supporting the significance of the problem?
- Demonstrate familiarity with the basic literature on this problem, by citing key reviews or studies that have been done, and identifying the strengths and limitations of these studies?
- Offer any necessary definitions (and justification) of key terms?
- Describe how prior work by you and/or others brought you to this point and what makes the proposed work the “next logical step?”
- Clearly identify the limitations of prior work (particularly those which you plan to address) but avoid unnecessary attacks on other researchers, methods or ideas?
- Summarize the implications of this literature/background for the proposed work, particularly those studies that provide the foundation for design decisions you have made?
- Make sure that your approach and/or critical design decisions in section D have been justified in either your background or preliminary studies section.

C. Preliminary Studies

Did you...

- Describe the experience of the PI and proposed team in terms of their specific training and experience in relation to the proposed interventions, field work, follow-up, data processing and analytic techniques? (If this is the PI’s initial proposal in the field, clearly identify how the PI will be mentored by someone established in the field..)
- Present the best available mini-evaluation for proposed issues to establish feasibility and likelihood of your approach?

- ___ Demonstrate familiarity with the proposed population and service systems through a discussion of the team's training, experience or preliminary studies?
- ___ Demonstrate competence/qualification to administer or evaluate the core interventions/services through a discussion of the team's training/experience and/or awareness of the key field's expectations (e.g., accrediting or professional standards)?
- ___ Demonstrate familiarity with and the ability to implement the proposed forms of data collection, focusing on success rate or preliminary studies?
- ___ Demonstrate the feasibility of and the team's competence in the proposed core analytic methods by discussing the team's training and experience, or present a mini-analysis?
- ___ Demonstrate an ability to use the proposed types of data and/or similar data sets?
- ___ Lay out a foundation for critical decisions in your research design, including definitions, selections of measures, sample, statistical transformations/ procedures and/or interpretations?
- ___ Establish the feasibility of new proposed interventions or quantitative data on standard/usual care that is already in practice.
- ___ Provide preliminary data on prevalence, effect sizes, or correlation over time to support the power analyses discussed below?
- ___ Show your competence to recognize and acknowledge the limitations of this work, provide a rationale for continuing in spite of them, and/or present fall back plans if things do not work out?
- ___ Pick one or two key tables or figures to demonstrate your ability to focus (vs. shotgun analyses of everything) and present information?
- ___ Conduct a quick survey, focus group, or interview with experts to address gaps in the available information, establish the need/significance, and/or feasibility of the proposed approach?
- ___ Summarize the implications of the preliminary studies for the proposed work, particularly those that provide the foundation for design decisions you have made?
- ___ Make sure that your approach and/or critical design decisions in section D have been justified in either your background or preliminary studies section?

D. Research Design

D.1 Overview of Hypotheses and Research Design

Have you ...

- ___ Reprised the problem in one or two sentences?
- ___ Translated your aims into testable hypotheses that identify the population, independent variables, dependent variables, expected effects, and comparison groups for analysis.
- ___ Clearly stated whether you are assuming a linear dose effect or different effects for different comparisons if there are multiple comparison groups?
- ___ If applicable, covered or discussed why it is not necessary to test all of the logical alternative hypotheses (e.g., A and A x B, but no hypotheses about B)?
- ___ Stated the general research design, number of people to be observed, and significant inclusion or exclusion conditions that impact generalizability?

- ___ Provided a simple table or figure summarizing the design?
- ___ Kept the design very focused on the core issue/problem and not diverted into a discussion of side studies?

D.2 Interventions (one for each major condition in an experiment [including standard] or types of interventions being studied)

Did you ...

- ___ Identify the theoretical underpinnings and basis for the proposed intervention?
- ___ Discuss each of the main components if you are proposing a multiple component intervention?
- ___ Identify procedures for encouraging completion and quantifiable goals for gauging how many people completed it?
- ___ Discuss how components and/or multiple exposures are expected to interact or produce dosage effects?
- ___ Provide a clinical contrast between comparison groups on critical dimensions (who, what, where, when, how often, how much) if there are two or more interventions?
- ___ Clearly discuss any rules for matching or tracking people within the intervention?
- ___ Include a manual for a standardized intervention (in appendix), establish that the procedures are already available or describe how they will be developed?
- ___ Discuss the degree of variability for a real world treatment and justify why this is important (e.g, for generalizability or to test a specific hypothesis)?

D.3 Communities, Treatment System and Programs

Have you ...

- ___ Described the communities and/or context in which the research will be conducted?
- ___ Described things like employment, economic trends, or social infrastructure issues that may impact outcomes?
- ___ Used local epidemiological data or data on states, counties and demographic subgroups to help define the context in which the research will be conducted and/or discussed their generalizability?
- ___ Identified any past history of collaboration between researcher and community/system/program and/or establish that all parties know what they are facing and will be able to make it work?
- ___ Discussed the organizational structure/relationships of the proposed programs to one another and to you?
- ___ Described the range of services being offered by the programs, with a particular focus on the extent to which they are standardized, or related them to standards like the Patient Placement Criteria of the American Society for Addiction Medicine, Committee on the Accreditation of Rehabilitation Facilities and/or Joint Commission on the Accreditation of Healthcare Organizations?
- ___ Described the size and caseflow of the programs, particularly if you need to recruit clients from them?
- ___ Described a state or other community in which a natural change is occurring, including

other trends, co-occurring events, or context which might impact the evaluation?

D.4 Participants

Did you ...

- ___ Describe the expected characteristics of the clients in terms of their demographics, distribution and/or experience with core predictors, interventions, and/or dependent measures?
- ___ List out your inclusion and exclusion criteria for participation?
- ___ Describe your procedures for recruiting clients, estimated flow and basis for estimation? (including the expected loss due to inclusion/exclusion criteria)?
- ___ Describe the proposed basis for stratification (sampling), blocking (randomization), or covariance (analysis of covariance) and the rationale (statistical, analytical, and/or logistical) for using them?
- ___ Describe your sampling plan, including any weights and/or adjustments that will be made and whether you need to correct for clustered variance as a result? (Make sure you have someone on staff who is qualified to do this!)
- ___ Describe the mechanism of randomization (e.g., list, envelopes, computer) and any kinds of block or special procedures that are planned?
- ___ Describe any special procedures for identifying and/or creating comparison groups? (If the comparison groups are to be created statistically, discuss the feasibility of the proposed approach and alternatives should it fail).
- ___ Discuss whether or not you are including minority, women and youth (under 21) in accordance with NIH guidelines; whether there will be sufficient numbers for analysis; whether you plan any subgroup analyses relative to them; and/or if any of your staff have special expertise in dealing with minority issues?
- ___ Clearly identify whether data collection is under the supervision of an institutional review board and whether it involves informed consent, is voluntary, coerced, and/or whether there are incentives, and/or the potential consequences of non-participation for the individual or program?

D.5 Data Sources/Instrumentation

Did you ...

- ___ Organize by sources (instruments), types of data (self-reports, collateral, other observations, laboratory, records), or types of measures (design variables, covariates, independent variables, dependent variables)?
- ___ Discuss the reliability, validity and/or quality of the available data (including references to published psychometrics, norms, and/or validity studies)?
- ___ Focus on the core scales or items that will be used in the analysis?
- ___ Discuss how you will resolve any differences in items or measures (e.g., records vs. self-report; urine vs. self-report) and/or any measurement checks you plan to do?
- ___ Say if you have possession and/or permission of all necessary instruments and data?
- ___ Propose qualified staff and an adequate work plan if you are developing or testing new measures, using incidence-based records, and/or doing economic analysis?
- ___ Avoid a "shotgun" approach to measurement with many redundant scales/sources that are

unnecessary for your aims or hypotheses?

D.6 Procedures

Did you...

- ___ Describe staff qualifications for line clinical or field positions?
- ___ Describe training, supervision, and quality assurance procedures?
- ___ Describe procedures for recruitment, randomization and follow-up not described already?
- ___ Describe procedures for tracking and conducting follow-up assessments?
- ___ Describe procedures for linking multiple data sets and/or converting incidence-type records to client or program-based records?
- ___ Describe procedures for physically handling data, in terms of editing and in terms of the database?
- ___ Describe how missing data will be handled?
- ___ Describe any special statistical procedures related to sampling or matching or selecting comparisons groups?
- ___ Describe any special statistical procedures that will be used, particularly if they are unusual or require the specifications of key assumptions (e.g., exploratory factor analysis) that vary?
- ___ Describe any statistical procedures related to time (e.g., ramp effects in medical claims records, time series, confounding events, cross-lagged correlations)?
- ___ Describe any qualitative procedures to be used? (e.g., Will focus groups be round-robin or open discussion? How will information be documented? Will the participants be able to critique the interpretation of what they said?)

D.7 Power Analysis

Did you...

- ___ Clearly state your assumptions about the number people per group, types of estimates or comparisons to be made, amount of attrition to be expected and size of any subgroups that will the focus on subgroup analyses?
- ___ If you proposed descriptive work, describe the size of the 90% (or better) confidence intervals, relative standard errors or some other measure of the precision you will have in main groups and any key subgroups?
- ___ If you are going to compare two groups, estimate the minimum detectable effect size (given your sample) or power to detect the hypothesized effect (given the sample size)?
- ___ If you are examining change over time, estimate (here or in the preliminary studies) the correlation over time and its impact on power?
- ___ Do power analyses that match your proposed measures (e.g., percentages for descriptive or logistic, effect sizes or R-square for dimensional or interval measures), analytic model (e.g., estimating correlation over time if repeated measure), and discuss the way you would actually use the tests (e.g., one vs. two tailed tests)?
- ___ Discuss specific steps you were taking to increase the design's sensitivity (e.g., stratification, blocking, use of scales, use of covariates)?
- ___ Select fairly high levels of precision/power (90-95% confidence intervals; 80-90% power), describe sensitivity to the range of likely scenarios, and/or include power tables showing a

variety of assumptions?

D.8 Main Analysis

Did you...

- ___ Organize your analyses by hypotheses or groups of hypotheses that will be analyzed the same way (vs. by analytic method).
- ___ Scientifically state what you expected to happen and why; how you were going to test it; and what your decision rules would be?
- ___ Match your methods to the hypotheses (e.g., using repeated measures designs if you have repeated observations, using MANOVA if you have multiple correlated measures, using path or structural equation modeling if you have multiple component, multiple dosage interventions, survival analysis if you have time to event, proportional hazard/markov if you have several stages of survival, or logistic regression if you have a single outcome)?
- ___ Clearly illustrate any proposed methods with substantive examples directly related to the proposed hypotheses?
- ___ Include a figure here (and/or in preliminary studies) to illustrate any complex analyses and show that you can present both substantive and technically correct information?
- ___ Acknowledge checks (e.g., assumptions of sphericity in multivariate methods) that need to be made and what you plan to do if there are problems?
- ___ Include staff who are specifically trained or have published papers using the kinds of analyses that are proposed (or at least through work in the preliminary studies)?
- ___ Discuss any statistical procedures or adjustments that will be used to address the use of multiple variables in the analysis?

D.9 Addressing Threats to Validity

Did you...

- ___ Demonstrate a familiarity with the general threats to a study's internal, statistical, construct, and/or external validity? (e.g., Campbell & Stanley, 1963; Cook & Campbell, 1979; Cronbach, 1982; Fairweather & Tronatzky, 1979; Rossi & Freeman, 1993; or reviews in most NIAAA, NIDA, and/or NIMH monographs on methods)
- ___ Discuss how you will assess the reliability and validity of your core dependent and independent variables? (e.g., validity of self reported substance use, validity of service log data).
- ___ Summarize the specific limitations of the proposed work and how you will measure, minimize and/or address them?
- ___ Describe any specific methodological studies you are proposing, particularly if you might publish them?
- ___ Address the integration of qualitative and quantitative information and how they will be integrated to plan and/or better interpret any findings?

D.10 Timeline and Dissemination Plans

Did you...

- ___ Organize by project year?
- ___ Summarize the implementation plan of all field work, analysis and publications?

- ___ Summarize when each major set of analyses/products will be produced?
- ___ Summarize where and how materials will be distributed, including through new technologies like websites?

E. Human Subjects.

E.1 Subject Characteristics:

Did you...

- ___ Say whether this is new or archival data?
- ___ Describe the sample characteristics, special features, and whether specific groups will be targeted?
- ___ Specifically address the inclusion of women, minorities, and youth (under 21) including whether there were sufficient numbers for subgroup analyses? (Do not simply cross-reference with section D – discuss in both places.)

E.2 Sources of Research Material.

Did you...

- ___ Describe the data sources (e.g., records, self report, laboratory tests, invasive procedures)?
- ___ Describe any data sets to be obtained and attach any necessary letters giving you permission to use them?
- ___ Give specific information and required approvals for any invasive procedures?

E.3 Recruitment and Consent Procedures.

Did you...

- ___ Summarize your procedures for recruiting clients and obtaining consent?
- ___ Include a copy of the consent form or protocol?
- ___ Make it clear whether consent was oral, written, voluntary, coerced, or related to contingencies (e.g., incentives, penalties)?

E.4 Potential Risks.

Did you...

- ___ Clearly identify the risk of disclosure, including kinds of information?
- ___ Discuss potential side effects?
- ___ Identify any potential complications from invasive procedures?

E.5 Risk Protection Procedures.

Did you...

- ___ Describe procedures for guaranteeing anonymity or confidentiality?
- ___ Describe steps to keep id/link file separate from the main data set (e.g., separate files, locked cabinets/rooms)?
- ___ Describe monitoring and checks done to avoid or detect any problems early?

E.6 Risk/Benefit Statement.

Did you...

- Demonstrate that the benefits outweigh the risks?
- Identify benefit to individual, future clients, and /or society?
- Include letters of approval from the state or other local institutional review board for human subjects?

F. Vertebrate Animals.

None generally in services research.

G. Literature Cited

Did you...

- Include only references for the cited research?
- Include the full reference, particularly if one of the team members was involved?

H. Consortium/Multi-site

Have you ...

- Discussed how the study will be organized and managed; particularly across organizational lines or when there are multiple sites?
- Discussed any contractual or consortium relationships and how they are related to scientific and financial oversight?
- Discuss how the data will be transferred between sites?
- Discuss how quality assurance will be managed across sites?
- Included letters giving you access to the proposed sites, data and population?
- Included an organizational chart for complicated projects?

I. Consultants

Did you...

- Include consultants for any area of competency where the staff do not currently have expertise?
- Include a letter and biosketch for the consultant?
- Discuss how you would be working with the consultant?

Budget

Have you...

- Identified the roles and qualifications of each staff person?
- Identified who is competent and/or will lead work in each of the core competency areas?
- If multiple sites, discussed how these people will work together (and preferably discuss their record of having done so in the past)?
- Provided a staff loading chart summarizing the commitments by staff person and year (remember the forms only show this for a single year and do not show consultants or subcontractors)?
- Provided a gantt chart showing the implementation of multiple stage work and when

- products will be due to help explain the budget?
- ___ Described your assumptions and provided a year-by-year count of the expected number of people in each type of data collection to explain variability in costs?
 - ___ Explained why any equipment and/or travel is needed, particularly if it amounts to more than a few thousand dollars?
 - ___ Met expectations for the branch in terms of year-to-year changes in the budget (e.g., many like to limit growth to 3% a year) and/or do you have contingencies if they want to cut 5-20% from the first year budget (a highly criticized, but very common practice)?
 - ___ Explained the indirect rate structure if it is complex?
 - ___ If applicable, described how you will waive fees or match the work with other funds?

Appendices

- ___ Have you included up to 10 peer-reviewed articles reflecting the team's experience in the core areas of competency and in terms of publishing?
- ___ Have you included copies of any intervention manuals, instruments, reports, and/or codebooks related to the proposed data?