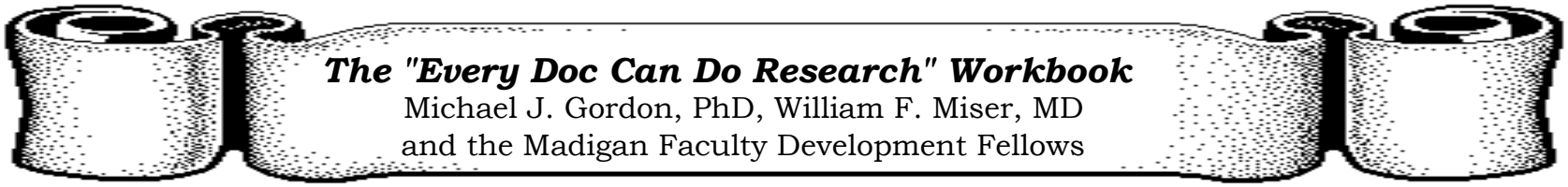


The "Every Doc Can Do Research" Workbook

Michael J. Gordon, PhD, William F. Miser, MD
and the Madigan Faculty Development Fellows

INTRODUCTION - An old Army saying goes something like this: "Prior Planning Prevents Poor Performance." Planning is essential to ensure a successful research project. A common reason a research project fails is inadequate pre-study planning and organization.

The purpose of this workbook is to provide you with a practical approach to planning and organizing your research project. Hopefully we can get you started thinking about the major steps that need to be accomplished in the planning phase. We encourage you to use this workbook as a starting point. As you make your way through this workbook, we have made recommendations at various spots on who you should contact for assistance.

We intend for you to write in this workbook. However, we realize that in some areas the space may be insufficient to fill in all of the details. If this happens to you, having a few extra sheets of paper to write on may decrease some of your frustration. You might also want to keep a separate notebook or diary in which you write anecdotes, remarks or subjects, comments by others involved in the project, or any other facts or observations which might help you to make sense out of the study.

It is also important that you finish this workbook entirely before you begin collecting any data. You will need to contact the Clinical Investigation Committee at your institution to determine exactly what they need you to submit to them for approval (research protocol). Using this workbook as a guide will get you well on your way toward completing that research protocol.

Good luck!

OTHER RESOURCES - Four books that you might find helpful in becoming more knowledgeable about research include:

- American Academy of Family Physicians - *Practice-Based Research in Family Medicine*, (can be ordered for nominal fee from the AAFP - we encourage you to buy this!)
- *Nursing Research - Principles and Methods*, Polit and Hungler ed, JB Lippincott Company
- *Epidemiology in Medicine*, Hennekens and Buring, Little, Brown & Company
- *Designing Clinical Research*, Hulley and Cummings ed, Williams & Wilkins

ACKNOWLEDGMENTS - Much of this workbook originated from the efforts of **Michael J. Gordon, PhD**, from the Department of Family Medicine, University of Washington, Seattle, WA. We would like to thank him for his inspiration and encouragement in modifying his original work. [Gordon MJ: Research Workbook: A guide for initial planning of clinical, social, and behavioral research projects. *The Journal of Family Practice* 7:1,145-160, 1978; reprinted by permission of Appleton & Lange, Inc.]

This workbook was modified by the Faculty Development Fellowship at Madigan Army Medical Center, Tacoma, WA:

- **William F. Miser, MD**, LTC, USA, Director, Faculty Development Fellowship - workbook editor,
- **Donald M. Bradshaw, MD**, LTC, USA,

- **Richard W. Emerine, MD**, CDR, FS, USN,
- **Brian R. Johnson, DO**, LTC, USA,
- **David C. MacDonald, DO**, MAJ, USA,
- **Robert C. Marshall, MD**, LCDR, USN, and
- **Mary J. Wyman, MD**, MAJ, USA.

Guy Runkle, MD, MAJ, USA and **Charles E. Henley, DO**, COL, USA also contributed to this workbook, while **Ted Epperly, MD**, LTC, USA provided inspiration for its completion.

Step #1 - Define Your Research Question

An essential ingredient in any quality research project is a well-defined research question. The question should be simple and specific - a small, clearly defined project is always preferable to one that is large and vague.

Begin By Asking the General Research Question:
(e.g. Should we treat pregnant women who are carriers for Group B strep (GBS)?)

As you complete this workbook, you will find it useful to rewrite (refine) your research question several times. Each revision should have greater precision and narrower scope in your search for an answer.

Step #2 - Hit the Library (Lit Search)

The next step is to learn as much as you can about what others have done (literature search and review). A good literature review lets you find out what is out there, helps you define your research topic, updates your knowledge about the subject in which you are interested (makes you an "expert" in that area), and may give you methodological tools to use in your study. To get the most out of your search, you need an effective plan.

Begin your search by looking at the references cited in recent textbooks and the articles in your personal library. You should also browse the current issues of pertinent journals in your medical library, and ask other providers for a chance to look at their journals and textbooks. You should next use a computerized bibliographic database from the National Library of Medicine (NLM, MEDLARS). The NLM has several databases dealing with ethics,

chemistry, toxicology, cancer, medical history, AIDS, and health planning and administration. Probably the most-often-used database from the NLM is MEDLINE, which contains most of the medical journal articles from 1966 onward. Another useful NLM database is CATLINE, which contains lists of books, monographs, government documents, statistical sources, and historical material. Finally, don't forget to look at non-medical databases such as Science Citation Index and others dealing with subjects such as biology, psychology, sociology, and education.

A medical librarian has the expertise to help you with searching these databases and is a valuable resource you should not overlook. However, if you do not have immediate access to a librarian, you can do the search yourself using a personal computer and modem. You can now do your Medline searches for free by going straight to the home page of the National Library of Medicine (http://igm.nlm.nih.gov/); simple on-line instructions guide you through the process of using on-line Internet Grateful Med. Another useful home page of the National Library of Medicine uses PubMed (http://www.ncbi.nlm.nih.gov/PubMed/); using this search mechanism requires a bit more expertise. Both of these home pages have a link to Lonesome Doc, a feature that allows users to order full-text copies of articles from a local medical library (local fees and delivery methods vary); users must register to use this service. If you don't have access to a computer or modem, you can always use the AAFP's **Huffington Library** (800-274-2237, ext 4402) which can help you with your search.

Although searching the NLM databases is extremely important, you will probably not find all of the important articles you will need. Studies have shown that only half of the relevant articles are typically retrieved at the beginning. As such, it is important for you to look for additional references in the bibliographies of the articles you initially find. Another useful search method is the ***invisible college***, which is the collection of "experts" in the field you are studying. Your search for the invisible college begins by asking the authors of the articles obtained in your initial search who they consider to be the experts in that field. You then ask those experts the same question, and repeat the process until you get to a handful of authorities, each of whom is aware of and refers to the others in that group as experts. This invisible college is probably the best source of unpublished and ongoing research in your area.

Once you have the list of articles from your search, your next step is to obtain and then review those articles. Reading the abstract will let you know if the article is pertinent to your study, or irrelevant (and thus thrown out). Once you have the articles you feel are pertinent to your study, you should then use a systematic way to read them.

(continued next page)

Step #2 - The Literature Search (continued)

As you critically read each article, ask the following....

- what was the purpose(s) of the study?,
- what did the author(s) find from their literature review?,
- are the hypothesis and question(s) similar to yours?,
- are the subjects in the sample representative of the people who should be studied?, are they similar to your population?,
- is the methodology of the study similar to what you want to use, and are there helpful tools that you might want to use?,
- what problems were encountered, and what were the limitations of the study?, and
- do the conclusions and recommendations follow logically from their results?

You may want to make notes on the article itself, or on a separate sheet of paper. When you are done reading these articles, you should have a good idea of what has been accomplished, how it was done, the problems that others have had in their studies, and how the results of your study can add to the existing field of knowledge. At this time you may also want to write a summary of your literature search, which would later serve as a basis for the introduction and discussion sections of your paper.

For additional information on how to conduct a literature search, we recommend the following articles:

- Miser WF: Critical appraisal of the literature. J Am Board Fam Pract 1999; 12(4):315-33.
- Greenhalgh T: The MEDLINE database. BMJ 1997; 315:180-3.
- Williams HA: Searching the literature creatively: updating your skills in reviewing the literature. J Ped Oncology Nursing 10(1):33-6, 1993.
- Schira MG: Conducting the literature review. J Neuroscience Nursing 24(1):54-8, 1992.
- **The Users' Guide to the Medical Literature** - superb JAMA series.....
  - How to get started. 270(17):2093-5, 1993.

- How to use an article about therapy or prevention: are the results or the study valid? 270(21):2598-601, 1993; what were the results and will they help me in caring for my patients? 271(1):59-63, 1994.
- How to use an article about a diagnostic test: are the results of the study valid? 271(5):389-91, 1994; what are the results and will they help me in caring for my patients? 271(9):703-7, 1994.
- How to use an article about harm. 271(20):1615-9, 1994.
- How to use an article about prognosis. 272(3):234-7, 1994.
- How to use an overview. 272(17):1367-71, 1994.

Step #3 - Justify Your Study

Based upon your literature search, evaluate your initial question and answer the following questions:

- Who cares about the answer?
- Is the question applicable based upon what is already shown in the literature?
- What is the current opinion about your topic? Is there a consensus, or is opinion divided?
- How important is it to have the right answer?
- Is the question you are asking unique, or has it been "beaten to death" already in the literature?
- What are the implications of various possible answers?

Write a paragraph to justify your study - consider the above questions, but feel free to modify or add to them. *(e.g. The literature justifies the use of intrapartum antibiotics in high-risk OB patients with GBS (pre-term, multiple gestation, fever, etc), but there is great controversy whether intrapartum antibiotics should be given to OB patients with GBS who have none of these risk factors. The majority of neonatal deaths from early-onset GBS disease occur in this latter group. No study to date has conclusively answered this question.)*

Based on the above, do you still feel that your study is justified? If yes, go on. If no, then either rework the question or write a review article on the subject.

Step #4 - Refine Your Research Question

Relook at your original research question - it is time to refine it based upon what you have found out from the literature review.

Define the Population to be Studied. *(e.g. pregnant women with Group B strep R-V cultures done at 28 and 36 weeks; term (38-42 weeks) delivery at our hospital; no risk factors such as PROM, multiple gestation, etc).*

Define the Period of Time for the Study. This may change as you proceed with this workbook, but it is important to think about it now.
(e.g. those who deliver at our hospital from 1 May 95 to 30 Apr 96).

Select the Variables to be Measured.
(e.g. demographics such as age, race, gravidity, parity; R-V culture results at 28 and 36 weeks gestation; labor data such as EGA, ROM length, meconium, fetal distress, type of delivery; treatment or no treatment with antibiotics; newborn problems; etc).

Change Nonspecific Variables Into Specific Variables That Can be Measured ("Operationalize Your Variables"). *(e.g. fetal distress = presence of FHR late decelerations, bradycardia, abnormal cord gas; early-onset GBS = positive blood, CSF or urine cultures for Group B strep in a neonate in first 48 hours of life; etc).*

Step #5 - Look at What Resources are Needed to Complete this Project

This is the appropriate time to see if you have the resources needed to successfully complete the research project.

Estimate the Resources Required to Measure Each of the Variables Mentioned in #4. *(e.g. time, money, cooperation with OB nurses on L&D, pharmacy, lab, clerical support, computer support, etc).*

Estimate the Feasibility of Conducting Your Study by Comparing the Resources Needed With Those Available To You.

Based upon the resources that will be required and those you have available, is the research feasible? If not, consider doing a multicenter study and asking others to help out. If it is feasible, then go on.

Step #6 - Refine the Question Again

Restate the Research Question in a Refined Form that Can Be Studied With Available Resources. *(e.g. Does intrapartum antibiotic treatment of term, low-risk pregnant women who are carriers for GBS decrease the risk of early-onset GBS sepsis in their newborns?).*

Step #7 - Write the Hypothesis

What do you think you will find? The hypothesis is a statement of what you predict or think you will find in your study based on knowledge of the field, logical analysis, and/or anecdotal observations. Although purely descriptive studies do not require a formal hypothesis, it is always wise to commit yourself to a set of expectations regarding your results.

Write What You Expect to Find From Your Study. *(e.g. I think the incidence of early-onset GBS disease will be decreased in the group treated with intrapartum antibiotics).*

What Are the General Relationships Implied By Your Hypothesis?
(e.g. intrapartum antibiotics is related to decreased exposure of GBS to the neonate; decreased exposure of GBS is related to less likelihood of GBS sepsis in the neonate)

	is related to	
	is related to	
	is related to	
	is related to	
	is related to	
	is related to	
	is related to	

Are There Any Specific Alternative Relationships or Explanations That Would Serve as Competing or Rival Hypotheses? (*e.g. Are there other possibilities or alternatives that could increase or decrease the incidence of GBS sepsis other than intrapartum antibiotics? I really can't think of any.)*

State Your Hypothesis in a Clear, Concise Sentence. (*e.g. Intrapartum antibiotic treatment of term, low-risk pregnant women who are carriers for GBS decreases the risk of early-onset GBS sepsis in their newborns.)*

Step #8 - Determine What You Are Going to Measure, And With What Instruments

Look at all of the variables that you need to measure in your study, and how you are going to measure them. *(e.g. neonatal weight measured by nursery scales in grams; GBS culture of the rectal-vaginal area; CBC using standard hospital lab equipment, EGA from maternal OB records, etc).*

Things to Be Measured or Counted	Proposed Instruments or Data Sources	Is This Available to You?

For those items just listed for which an instrument or data source is *not* readily available to you, what are the critical characteristics of the instruments to be found or developed. *(e.g. if a glucometer is needed, is there a specific brand that you need? how accurate does it need to be? is cost a consideration?, etc)*

Proposed Instruments	Critical Characteristics

For each instrument, address each of these questions:

- ***Reliability*** - how closely do repeated observations (by different people, at different times, etc) of the same thing agree with each other?

- ***Validity*** - With what assurance do we know that the instrument is measuring what we believe it is measuring?

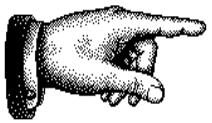
Mark each instrument above with an ***R*** if you believe reliability is a problem and a ***V*** if you believe validity is a problem. Also include those instruments that you readily have available to you.

Stop! Is there a problem with the reliability or validity of the instruments or data sources that you will be using? If so, you need to change something so that the data you obtain will be both reliable and valid. You may need to seek help in this area if you are unsure what to do.

Step #9 - Develop the Research Design

The design of the study refers to the way in which you will study the relationships between and among variables that you plan on measuring.

At this stage, we encourage you to call an experienced researcher, especially if all of this is new ground. It is wise to seek competent help in preparing a research design. Choices among the designs will always require compromises between the practical and the ideal. Well-designed research, like anything else designed well, should be more efficient and better suited to your needs than a haphazard approach. Poorly designed research may be inefficient or, even worse, may make it impossible for you to analyze the data legitimately.



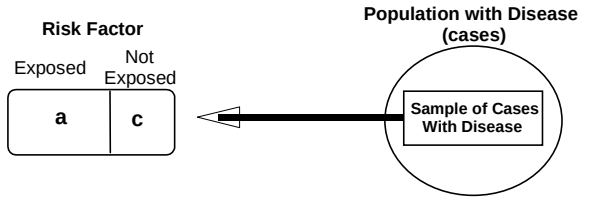
The following are common research designs encountered in family practice research. These are listed to give you some ideas, but you may want to refer to one of the resources mentioned at the beginning of this workbook.

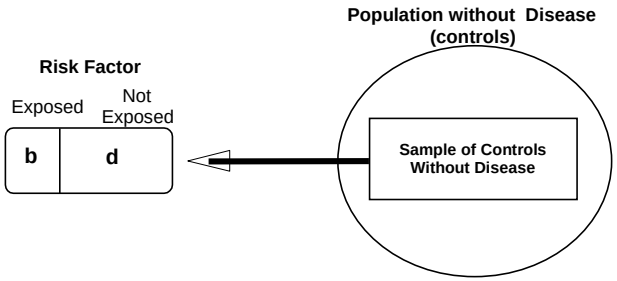
Descriptive Studies - Any research activity in which the investigator gathers data from a portion of the population (the sample) to examine characteristics such as what people do, what people plan to do, what people know, opinions, attitudes, values, etc. Information is also obtained from populations about the prevalence, distribution, and/or interrelations of variables. The researcher does not manipulate any variables, but only describes things. *Example: Surveying all AAFP members on their satisfaction with managed care.*

Observational Studies - As in descriptive studies, the investigator does not alter or manipulate any variables and does not randomly assign subjects to groups, but does analyze the data using statistical tests. There are three (3) major types of observational studies: (a) ***case-control***, (b) ***cross-sectional***, and (c) ***longitudinal (cohort)***.

Case-Control Studies: Typically retrospective, you identify groups of subjects with and without the disease you are studying, and then look backward in time to identify the presence or absence of risk factors. *Example: Vaginal cancer and maternal exposure to DES,*

Disadvantages include: (1) potential bias from sampling two populations, (2) does not yield prevalence or incidence, (3) selection of controls may be a problem, and (4) exposure data may be subject to biased recall. Strengths include: (1) useful for studying rare conditions, and (2) relatively inexpensive and quick to complete.





Case-Control Study
A retrospective study in which the investigator selects a group with disease (cases) and one without disease (controls) and looks back in time at exposure to potential risk factors to determine causation. Data are typically analyzed using the odds ratio.

Odds Ratio (OR) is the measure of strength of association. It is the odds of exposure among cases to the odds of exposure among the controls.

	Cases	Controls
Exposed	a	b
Not Exposed	c	d

$$OR = \frac{(a/a+c)/(c/a+c)}{(b/b+d)/(d/b+d)} = \frac{a/c}{b/d} = \frac{ad}{bc}$$

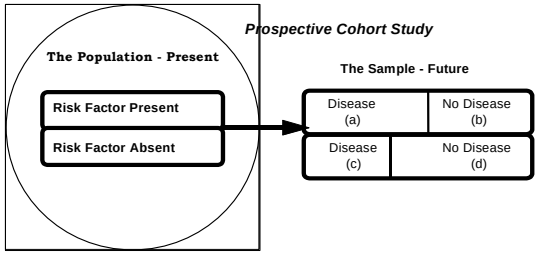
Cross-Sectional (Prevalence) Studies: You make all your measurements at once (one point in time) looking at both disease status and exposure factors. *Example: What is the prevalence of GBS early-onset disease in my hospital and which infants are at risk?*

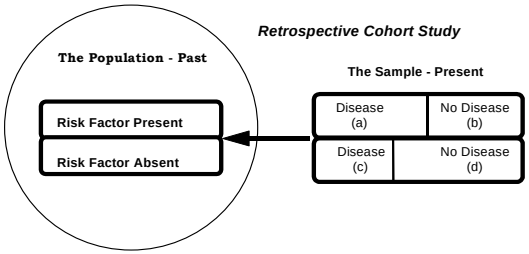
Disadvantages include: (1) you can't establish causality - you don't know if the exposure preceded the outcome, (2) does not yield incidence of disease, and (3) not feasible for rare conditions. Strengths include: (1) yields prevalence, (2) may study several outcomes, and (3) relatively inexpensive and quick to complete.

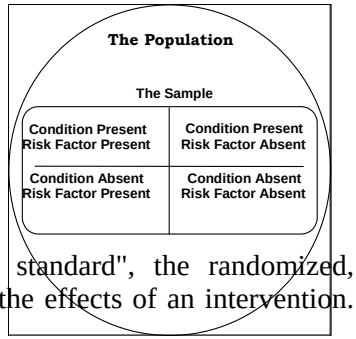
Step #9 - Research Design (Continued)

Cohort Studies: A cohort is a group of subjects who are followed over a period of time. There are two (2) basic types: (1) prospective cohort study (the investigator defines the sample and measures variables before any disease has occurred), and (2) retrospective cohort study (the investigator defines the sample and measures the variables after the diseases have occurred). *Example: Women born in 1950's currently on oral contraceptives, variable = smoking; outcome = myocardial infarction.*

Disadvantages include: (1) need large numbers, especially for rare diseases, (2) potentially very expensive, (3) time consuming, and (4) attrition may be a problem. Strengths include: (1) time sequence of exposure and outcome is known, (2) can directly measure the risk of a bad outcome, (3) can study many outcomes of a single variable, and (4) good for occupational diseases.

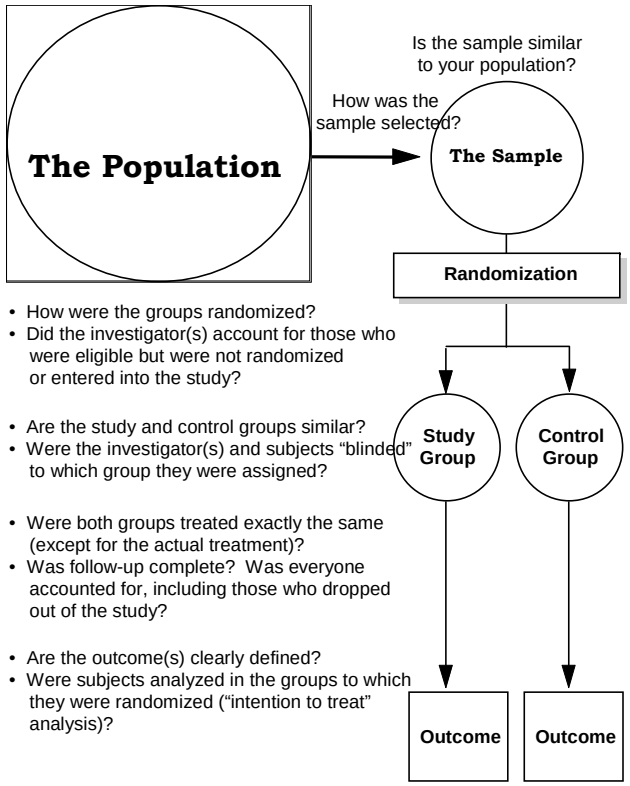






Experiments: Often considered the "gold standard", the randomized, double-blind trial is the best way to establish the effects of an intervention.

The investigator, through the study design, has control over which study subjects are exposed to the factor of interest, and makes exposure assignments for purposes of the study. This is the strongest design for establishing causal relationships. However, experiments are also the more difficult and expensive of the types of studies. Also, some experiments can't be ethically done - for example, one can't randomly select subjects to enter a smoking group.



There are many other types of research designs, but these are by far the most common, and should give you a good foundation when collaborating with others on which study design is best to answer your research question.

You can also help identify the issues that your design should address by considering carefully each of the items in steps #10-12 below.

Step #10 - Select Your Sample(s)

Describe the characteristics of the people (or the subjects) who will be eligible for participation in your study. *(e.g. all singleton term (38-42 weeks) pregnant women who are known R-V GBS carriers, who have no known risk factors, and who deliver at our hospital during the study period).*

Describe the characteristics of the people (or the subjects) who will be excluded from participation in your study. *(e.g. OB patients who are preterm (before 38 weeks), have a fever, have multiple gestation, who have PROM, etc).*

Describe the population (beyond your sample) to which you wish to generalize conclusions. *(e.g. the results of this study will apply to all term, pregnant women with GBS who are otherwise considered low-risk; etc).*

Determining Sample Size (How Many Need To Be In Your Study?) One of the most frequent questions asked is "how many do I need to include in my study?" Before this can be answered, you need to answer several questions. Two of the most important considerations in determining sample size are how much money you have to spend, and how much time you can commit. The larger the sample, the more it will cost, both in dollars and time.

Increases in sample size increase the precision of the research. A large sample should allow you to detect more subtle (but perhaps less clinically important) relationships.

It's time to talk to someone who can help you determine the sample size. A statistician at your institution, someone with a strong background in research, or someone from the Clinical Investigation Committee of the AAFP should be able to help you with this.

How many will you need in your study? _____

Some things you'll need to determine when figuring out the sample size are the following:

- How sure do you want to be that the results you find did not occur by chance alone? (e.g. are you willing to take a 5% chance (that is, $p < 0.05$) - most people arbitrarily set this at either 0.05 or 0.01.

  _____

- If you find no difference in relationships, how sure do you want to be that you had a large enough sample? - this is referred to the power of the study; most people set this at 0.80

  _____

- What size difference do you expect to find between the two groups? You will need a larger group to find a significant difference in weight of 2 grams as opposed to 2 kilograms. This expected difference may come from pilot studies, other research, or your best guess.

  _____

Step #11 - Develop the Research Protocol

How Will You Select the Sample? Will you sample all those who attend a certain meeting (convenience sample) or will you randomly pick them, and if so, how will you do the randomization? *(e.g. All OB patients presenting to L&D with the entrance requirements over a one-year period of time).*

Will You Divide Your Sample Into Groups? If So, How? What criteria are you going to use to determine who goes into what group, etc? and how will you make sure that the groups are similar except for the variable that you are studying? *(e.g. Once identified and agree to enter the study, she will be randomly placed into either a treatment group or a control group using a pre-determined table of randomization).*

Describe what will happen to each group. (It helps to draw a flow diagram, an example of which is....

Describe what will happen to each group:

Who Will Gather The Data, and How? *(e.g. Upon entry into the study, the nurses will complete a data sheet; the investigators will then review the maternal and newborn charts after delivery.)*

Step #12 - Eliminate or Control the Biases

Bias refers to sources of systematic error that may affect your study results. Unless adequately controlled, bias may render your results uninterpretable. You need to give specific attention to each of the following potential sources of bias. As you control for the most serious of these biases, your study design will evolve.

Effects of Historical Events - Can you anticipate events such as personnel changes, remodeling plans, interference by nonparticipants, etc, that will take place during your data collection phase and which might affect the results? If yes, describe.

Effects of Maturation - If subjects are to be observed over time, are there changes that might result merely by normal development, growth, natural course of illness, etc? If yes, describe.

Effects of Repeated Measurement - If the same measurements are repeated on subjects, are they likely to remember past responses, prepare differently for the next session, relax procedures? If yes, describe.

Instrument Decay - Is it likely that the test equipment will wear out, observers get bored, protocols get short-cut by investigators, etc? If yes, describe.

Effects of Statistical Regression - If subjects are chosen because they lie at the extremes of a distribution (e.g. severe hypertension, low compliance with medicine), subsequent measurements will tend to be more nearly average, for purely statistical reasons. Are your subjects chosen or assigned to groups on the basis of their "extremeness"? If yes, describe.

Subject Selection - Is there anything in the selection of your sample or assignment of subjects to groups that makes one group of subjects unintentionally different from other groups? If yes, describe.

Loss of Subjects - Subjects lost to attrition (e.g. moved, died) may be different from those who remain. Is your study jeopardized by this possibility? If yes, describe.

Investigator Bias - Are you in a position to unintentionally "shade" results to confirm your hypothesis or to influence subjects by your attention, attitude, etc? If yes, describe. (note: blinding the investigator will minimize this bias).

Stop! Look at the above biases - can you change your study design so that you minimize them? The more bias you can control through your study design, the more "faith" you can have in accepting your results as being true.

Step #13 - Identify the Limitations of Your Study

After struggling to develop a study design that is feasible and minimizes the most troublesome sources of bias, you may still be left with inadequate control over other sources of bias. Use the space below to identify the remaining potential sources of bias.

Potential Sources of Bias Remaining

Even unbiased studies have limitations in their generalizability. For example, a study done on lower income patients may not apply to higher income patients. To what kinds of people beyond your study sample can you justify generalizing your conclusions? (It may be easier to identify individuals for whom your conclusions do not necessarily apply).

Limitations to Generalizability

Step #14 - Develop Data Collection Forms

Spend some time developing the forms that you will use to collect your data. Look at what data you need to record (go back to Step # 8). When developing your form, you may also want to start thinking about what type of computer data base program you want to enter the information into, and develop the data base and the form so that you can easily transcribe the information from the form into the computer. Before launching into the study, it also helps to "pilot" the form on a few subjects/records to work out any bugs, etc. For example, if you are collecting data from an OB chart, you might want to have the information on the form follow the information as it is laid out in the chart, so you can easily go from the front of the chart to the back of the chart (and not have to flip back and forth through the chart). It also helps to code your form so that you can easily enter the information into the computer database. For example, 1 = male, 2 = female.

Use separate sheets of paper to develop your data collection forms, and have others go over your form to make sure it is easy, simple, complete, and accurate.

Step #15 - Reporting of Results

Are you collecting the right type of information? Based upon the data you want to record (Step #8), and your data collection form (Step #14), use the space below to sketch summary data tables and/or graphs which you would expect to use in presenting your results. You may include simulated results of the kind you hope to find.

Step #16 - Pick Your Statistics

Most people shudder at the thought of statistics. However, there are some individuals who love the topic. It's time to find those individuals so you can discuss what types of statistical analyses you will want to perform in your study. *Always* seek competent consultation at this stage or there may never be any analysis worth doing.

To determine the types of statistical analyses, you will have to look at the type of data and variables you will want to compare. There are four (4) basic types of data:

- **Categorical (Nominal) Data**: Data that is in a category or name only, and which values can NOT be placed in any order. Examples include gender, race, religion, and yes/no types of answers.
- **Ordinal Data:** The different values of the variable are ordered, but the difference between each value is NOT necessarily the same. An example is one's sense of well-being: good (1), fair (2), or poor (3).
- **Interval Data:** This is ordered data in which there is an equal distance between successive levels. An example is temperature - the distance between 37 to 38 degrees Celsius is the same as 38 to 39.
- **Continuous Data:** This is numbered data that may be able to go to infinity. Examples include age, weight, and gestational age.

There are also four (4) different types of variables that you will be measuring:

- **Demographic Variables**: Data that describes the characteristics of subjects such as age, sex, race, previous treatments, etc.
- **Independent Variables:** These are the variables that you control as an investigator, such as type of treatment given, duration of therapy, or other exposures you may *assign* to subjects.
- **Dependent Variables:** These are the outcome variables that you will measure that may be potentially related to or caused by the above variables, such as speed of recovery, patient satisfaction, etc.
- **Confounding Variables:** These are variables that may be associated with the independent variable, and may affect the dependent variable. For example, coffee drinking (independent), smoking (potential confounder) and death from MI's (dependent).

Look at all of the information that you will collect or measure in your study (from Step #8) and determine what type of data and what type of variable each one is.

Things to Be Measured or Counted	**Type of Data**	**Type of Variable**
e.g. neonatal weight	*continuous*	*descriptive*

Based on the above, and depending upon what you want to compare, the statistician can help you determine what types of statistical tests you may want to use.

Step #17 - Administrative Arrangements

Lack of attention to administrative details sometimes destroys even the most elegantly designed studies. For example, failure to coordinate ahead of time with nursing staff may mean that valuable data is never collected. At the completion of this workbook, you will need to complete a protocol as established by your Clinical Investigation Committee. In order to have this protocol approved, you will need to ensure that all of the administrative details are planned, and that all parties (e.g. the lab, nursing, etc) have agreed to help you with your study.

Use the space below to describe administrative arrangements that you have made. *(e.g. money, equipment, supplies, space, printing, consultation, computer programming, postage, telephone use, etc).*

If your study deals with human subjects, you will probably also need to develop an informed consent form. Ask your Clinical Investigation Committee if they have an example format (many will have a blank form on computer disk that you can just fill in the blanks).

As you finalize your study, you will also want to outline who you will need to solicit help from (e.g. laboratory personnel, nursing, pharmacy, etc). Use the space below to identify those individuals who you should touch base with.

Touch Base With.....	Regarding.....

At this stage, you also may want to consider applying for a grant (money) to help pay for supplies or extra warm bodies to help you with your study. An accompanying section (step #19) explains the resources available that might be able to help support or fund your study.

Step #18 - Protocol Approval and Initiation of Study

Once you have your protocol approved by your Clinical Investigation Committee, you

are finally ready to start collecting data. The hard work is now done (the planning stage) and you are ready to have some fun. Good Luck!

An Addendum Step - Consider Asking for Money (Applying for a Grant)

Getting money from a grant sounds wonderful, but it can be a two-edge sword. Along with the money comes complexity - you may get people that are difficult to manage, you have to train people, and you have to deal with the bureaucratic red tape and other administrative burdens. So, sometimes the "best" way is to just do the study yourself without outside funding.

Although a grant may speed things up because you get additional help, it does nothing about the **quality** of the project. As such, it is important that your research project be well thought out (which is accomplished by following the steps in this research workbook) before you consider applying for a grant.

Space does not permit us to go through the entire granting process. If you are interested in applying for a grant, you should contact someone in your institution who has gone through the process. Mentorship in this area is extremely important, and having someone to help who is experienced in writing and managing grants is essential. Also, one needs to have "thick skin" when applying for grants since money is often limited and a majority of grant applications are initially rejected.

One important source for grant money is the American Academy of Family Physicians (AAFP). The AAFP has three programs available - the AAFP Grants for Family Practice Research, the McNeil Awards for Clinical Research by Family Practice Residents, and the Student Research Assistantship. The actual amount available depends upon the project. Further information and applications for a grant proposal from the AAFP can be obtained by calling (800) 274-2237, ext 4442.

Other sources of grants that may be applicable to family physicians include the following...

Grant Source/Name	Short Description	Phone #
Academic Research Enhancement Award	Supports new research projects or expands ongoing research activities proposed by faculty members of eligible institutions in areas related to the health sciences.	(301) 594-7248
William T. Grant Faculty Scholars Program	Provides support to junior faculty members in research relevant to the well-being, and health development of children, youth and adolescents.	(212) 752-0071
NRSA Fellowships for Research Training in Primary Care Disciplines	An NIH grant that supports additional research training in the primary care field.	(301) 496-7441
Mental Health Services in General Health Care Research Grants	Encourages research on mental disorders in primary care, particularly research that focuses on the nature, recognition, classification, treatment and outcomes of people with mental disorders.	(301) 443-1330

To obtain additional sources for grants, your medical librarian can help you find a grant directory that lists other granting organizations.

Special Steps – Operational Medicine: Research from a deployed location

References: USAFP Newsletter (Spring and Winter 2007, Winter 2008)

Authors: Brian V. Reamy, MD; John E. Baker, JD; Eric Shuping, MD, MPH; Paul Lewis, Ph.D., FNP;
Compiled by: Brian K. Unwin, MD

Conduct of research in the deployed environment requires additional attention to unique IRB approval mechanisms. ALWAYS learn about requirements and inform Chain of Command prior to conducting research.

Points/Issues to ponder:

- Research relevant to deployed warfighters deserves dissemination and publication
- Research must have IRB approval to be published
- Research should not generally be conducted without IRB oversight.

General Guidelines:

- If an IRB is present within your operational area, follow its procedures
- Know that there are special review procedures unique to special operations forces. Contact a SPCOPS surgeon for information.
- Work with Chain of Command to see if service or DoD-level IRB has been designated.
  - Complete DoD training for protection of human subjects, such as the CITI program (contact your MTF IRB office).
  - If there is no IRB, approval for collection and use of data comes from the Operational Commander under whom the work is being performed.
- All approvals should be documented, and studies should be continuously reviewed by the IRB until the study is closed.
- Approval for any presentation or publication of research occurs at local Public Affairs Officer (PAO) or local Commander. Sensitive material may require approval from a higher headquarters or DoD level. Guidance example: OTSG/MEDCOM Policy Memo 05-002.
- Consider collaborative research with other investigators with IRB access. Example: collaborate with USU investigator and use its IRB for oversight of the study. USU may be able to identify other IRBs that could be used for the study.

Specific Research Steps for Operation Iraqi Freedom and Iraq Theatre of Operations (ITO): Deployed Combat Casualty Research Team (DC2RT) purpose is to help facilitate research in the Multinational Corps-Iraq (MNC-I) theatre, and to serve as a conduit to gain IRB approval of research protocols. The process for Protocol Development and Approval is:

- Develop the idea: DC2RT can help refine questions and focus of proposed study, and guidance for what should be included in the protocol
- Submit the protocol to DC2RT: For Army personnel in the MNC-I area—submit through DC2RT; other forces not required to go through DC2RT. However, DC2RT will provide research assistance to all services. Protocol is reviewed and recommendations made to facilitate approval
- Submit the protocol for scientific review: DC2RT forwards the protocol to the US Army Institute of Surgical Research (US Army ISR) for scientific review by subject matter experts. Recommendations for improvement are returned to the investigator to strengthen the study.
- Obtain appropriate signatures: The Principal Investigator (PI) and Associate Investigators (AIs), and military treatment facility (MTF) commander all sign the research protocol. The DC2RT is responsible for obtaining signatures from the MNC-I Research Director and the MNC-I Surgeon. All signatures must be obtained before an approval start letter can be issued.
- Submit to the MNC-1 Research Director and MNC-I Surgeon: The MNC-I office screens all protocols for scientific merit and feasibility of conducting the research in theatre.
- Submit the protocol: Once all steps are completed, DC2RT will submit the protocol to Brooke Army Medical Center (BAMC) IRB for approval. The approval authority for all Army research in the MNC-I is the BAMC IRB. BAMC IRB will also process other research protocols submitted by other services.

The process from scientific review to IRB approval has averaged about 30 days. Protocols can be developed pre-deployment. No IRB process currently exists for the Afghanistan Theatre of Operations. Current POCs for the ITO include Denise Hopkins at denise.hopkins@us.army.mil, MAJ Matthew Griffith at matthew.e.griffith@us.army.mil DSN: 318-239-7705 of the Dc2RT. LTC Ronald Ross at Ron.Ross@us.army.mil is the MNC-I research director (DSN: 318-822-4679)