Research Methods Case Study Role Play

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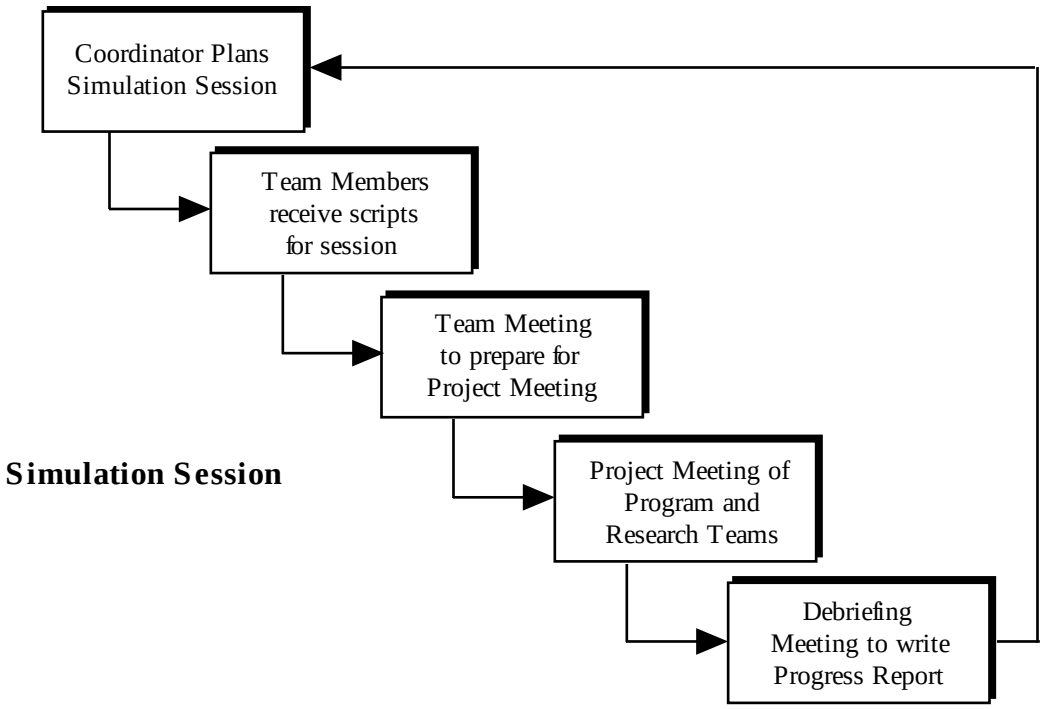
This manual contains comprehensive instructions for a semester-long role play of a complete research project designed to illustrate some of the major issues and challenges in conducting applied research in real-world contemporary settings.

Contents

General Instructions

This case study utilizes a "scripted case study" or "scripted scenario simulation" approach to learning. Students will be divided into two groups of 5 team members each. One group will play the roles of program related people (the Program Team) while the other will act the parts of the researchers (the Research Team). Each team will decide which roles each player will play and will develop their own internal rules for governing themselves (e.g., who will lead discussions, take minutes, etc.). The final product of this case study will be a class presentation in which the research team will present their research methodology and the program team will act as critical discussants.

For each simulation session, each student will be given a short description of their role for the session. This description will outline what stance that student should take for the simulation session and give some hints of what you might expect. The simulation session itself is essentially a meeting (called a Project Meeting) between some or all of the members of each team. Prior to each Project Meeting, each team will probably want to have a Team Meeting to plan their strategy for the upcoming session. After each Project Meeting, each team will have a Debriefing Meeting to write a short Progress Report describing the issues of relevance. The Progress Report will be used by the Coordinator to prepare the scripts for the next simulation session. The structure of this project is illustrated in the following diagram:



Notice that the basic structure is iterative -- it loops over and over until the case study ends.

Although the general case study description and the session scripts will constrain the simulation to some extent, the teams are free to be creative within these constraints. Both teams are expected to draw on class materials -- lecture notes and readings -- in preparing for each session, and teams are free to utilize any other resources to enhance their project performance (e.g., draw on materials, resources or technologies not directly covered in class).

Both teams need to be aware of the possibility that at any time the Coordinator may introduce unanticipated events and issues from the "outside world" which may affect or seriously alter the direction of the case study. If so, this information will be given to teams when they receive their scripts for the next session.

Reporting

There will be three written reports (minimally) from every Project Meeting:

1. **Questions**. A list of questions for the Case Study Coordinator from your team. These will usually be factual in nature. For instance, you might want to know how many hospitals are in the NortheastNet. Before submitting questions, however, you should check to make sure that you haven't already gotton the information. Sometimes only one person will be given information in their script (sometimes it might be a person on the other team). If you should already have the information that you request, the question will not be answered by the Case Study Coordinator.

2. **Minutes**. A list of key facts which are discussed by members of both teams. Obviously, we can't keep track of every little detail and I do want you to be creative in making things up. But I must know about the crucial details. For instance, if in the meeting you want create some facts about some of the roles (e.g., that the PD and CC have the same birthday), that's of no importance to the simulation. However, if you discuss details about the demographics of the metropolitan area or how many hospitals are in NortheastNet, I have to know this. Good detailed minutes from each team for each meeting would be sufficient for this task. Indicate on the minutes which member is making what points (e.g., PD:). If you inadvertantly introduce some facts into the case study which are not consistent or are likely to lead you far astray of what I want, I will find some way to correct you and let you know. Each team should submit their own version of the minutes.

3. **Assignments**. A list of assignments for each person on your team. Assignments can range widely from person to person or from session to session. Here are some ideas of what might constitute assignments (feel free to add your own ideas):

    - Relevant readings (very often you will need to read some sections of our texts or even sections of other books or articles)
    - Prepartion of a presentation (you might need to prepare a short presentation for the next meeting)
    - Writing (you might need to write a short position paper/memo either for internal team record keeping or for the next project meeting)
    - Computer work (you might need to run some sample or test analyses)
    - Interviews (you might need to interview a member of the other team or interview an "outside" expert for assistance -- e.g., another Cornell faculty member, or an expert in the field)

    Very often an assignment will be given (or implied) in your script for the week (e.g., a recommended reading).

Each team will therefore need to submit these three reports after each project meeting. **All reports must be typed.** You can decide internally how you want to divide the workload. Make the reports as short and concise as possible without leaving out details. All reports are due by Friday afternoon, 3pm, of the week in which the meeting is held. Each report must be clearly labeled with the Type of Report (i.e., Questions, Minutes, or Assignments), the Project Number/Name (this will be assigned to each project of two teams), the Team Name (i.e., Program or Research) and the Session Number.

Final Presentation

The final presentation for the entire project will be no more than a half hour long, with fifteen minutes allocated to each team. The research team will go first and will present the final methodology which they selected, along with a discussion of some of the reasons for their recommendations. The program team will

then have fifteen minutes to raise issues or questions regarding the acceptability of these recommendations and to critique the overall approach.

In addition, each team must hand in a complete team log which should be kept throughout the project. The team log should simply be a compiled list of team minutes, notes, relevant materials, presentation materials, and anything else of relevance. Note, that this is not a term paper. You are not to write anything new or special for this log. The log simply provides a record of all internal team documents over the life of the project. It is the documentation which you naturally generated over the course of the project. Consider it an appendix of technical, internal materials. All materials in the log should be placed in a notebook. The only thing you must supply is a table of contents listsing each item in the log in the order in which it appears.

Roles: The Cocaine Treatment Study

The Cast of Characters

The ten team members are described below. For each, some brief biographical information is presented and their role in the project described. Also, I've presented some personal observations about each in parentheses!

The Program Team

Role	*Description*
Project Director (PD)	The Project Director has a Ph.D. in Clinical Psychology and has been working for the past ten years in drug abuse treatment and research. The PD is the major initiator of this project , wrote the grant proposal, and contacted the Coordinating Consultant on the Research Team. (PD is a real obsessive-compulsive! A real stickler for details, but also with a sense of vision. A good group facilitator and manager.)
Medical Consultant (MD)	The Medical Consultant has an M.D. and is well-trained in clinical medical research. The MD has conducted conducted research for major pharmaceutical companies and has served as Chair of the National Science Foundation's Panel on Medical Research Quality. (The MD is the PDs good friend and trusted advisor. Tends to be a real "hard-ass" when it comes to research. Really believes in the importance of the randomized clinical research model. Aggressive in group meetings.)
Grants Officer (GO)	The Grants Officer is the major liaison between NIDA and the project. The GO has a Ph.D. in Social Work and has supervised grants for nearly seven years. (A real bureaucrat. The GO's heart is in the right place, but refuses to take any initiative without checking with higher-ups in the agency first. Not likely to negotiate on key issues on which the agency has strong positions.)
Hospital Administrator (HA)	The Hospital Administrator has a Master's degree from the Sloan Health Administration program at Cornell University and has been CEO of Central Hospital for eight years. In addition, the HA is Chairperson of NortheastNet, the consortium of hospitals which is cooperating in this project. (A nice, friendly person; good to have at meetings. Has a relaxed way of interacting. However, can be a real stickler when it comes to the Hospital's bottom line.)

Patient Advocate (PA)	The Patient Advocate has an M.S.W. and is currently employed by the Metropolitan Patient's Rights Group (MPRG) which is an advocacy group dedicated to ensuring that persons with drug dependencies don't get "screwed" by the medical/legal establishment. (An intelligent adversary who thoroughly believes in the cause. Always takes the patient's point of view in discussions. Is very cynical about medicine and medical research.)

The Research Team

Role	*Description*
Coordinating Consultant (CC)	The Coordinating Consultant has a Ph.D. from the Program in Evaluation and Planning (PEP) at Cornell University and has been conducting research and consulting for six years. This consultant was the first contacted by the PD and advised the PD on the selection of the other consultants on the Research team. (Has outstanding research skills. Has great management ability and is well able to lead a discussion. Is eclectic in methodological tastes -- likes to mix methods.)
Design Consultant 1 (DC1)	The Design Consultant 1 has a Ph.D. in Psychology and studied research design at Northwestern University with Donald T. Campbell and Thomas D. Cook. The DC1 specializes in quasi-experimental alternatives to randomized experiments. (Somewhat of a snob -- constantly quoting Cook and Campbell! The DC1 knows quasi-experiments inside and out. Doesn't care much for qualitative methods.)
Design Consultant 2 (DC2)	The Design Consultant 2 has a Ph.D. from the University of Chicago in Evaluation Research and has studied with the leading researchers in the field. The DC2 specializes in the theory of research validity as it applies to research design. (A very confident person, interacts well with others. Sees everything in terms of validity issues and threats to validity. Will use qualitative, quantitative or any other kinds of methods as long as they help minimize threats to validity.)
Measurement Consultant (MC)	The Measurement Consultant (MC) received a Ph.D in Applied Measurement from the University of Michigan. The MC is well trained in the development and use of scales in social research. (A very precise person. Likes to emphasize the reliability/validity of measures and statistical power issues. Has some familiarity with sampling theory and methods. Has some computer skills.)

Statistical Consultant (SC)	The Statistical Consultant has a Ph.D in Biometrics and Statistics and has consulted on statistical matters with Federal agencies and numerous medical research groups. The SC's specialization is the statistical analysis of quasi-experimental research designs. (Has good computer skills and knowledge of regression analysis. Very opinionated on statistical issues -- sees everything as a statistical issue. Not a fan of qualitative research.)

Session #1: Cocaine Treatment Study

Overview

The National Institute on Drug Abuse (NIDA) has just awarded a grant to the College of Health and Human Service Studies of the Metropolitan University. This college has programs in the social sciences and social services and in nutrition. In addition, it has close working relationships with the Medical School of the University. The University is located in a major metropolitan area (population greater than one million) in the Northeastern United States. Here is the Abstract of that proposal:

Abstract

Cocaine abuse has reached epidemic proportions in the United States. Despite the scale of the problem, little is known about effectiveness of treatments. This application proposes to determine the comparative efficacy of two prevalent forms of treatment, inpatient and outpatient, for persons with dependence on cocaine. The sample will consist of persons who are in the work force (blue collar to professionals) who seek treatment in the private non-profit sector. Subjects will be assessed on multiple occasions, including before and after treatment. Two major categories of outcome will be assessed: drug use, including use of cocaine, alcohol and other drugs; and psychosocial functioning, including functioning in the areas of employment, family and other social relations, and health care. A sample of men and women throughout the metropolitan area, from 21 to 58 years of age, who enroll during the next five years in inpatient or outpatient treatment for cocaine dependency will be recruited into the study. The study will be conducted at member programs of NortheastNet, an extensive network of hospital-based chemical dependency recovery services that provides care to over 50% of the residents in the metropolitan area.

The Project Director has decided to utilize research consultants to advise on technical research methods and statistical analysis issues.

This will be the first meeting of all parties to the Cocaine Study. The goal of this meeting should be to become acquainted and gather essential information. The PD will have primary responsibility for conducting the meeting. Since time is short (isn't it always!) the PD will need to get right down to specifics and discuss the major issues which are of concern in planning the research. There should be an opportunity for the Research Team to ask questions of their own as well. While the discussion may get as far as discussing some methodological options, it is unlikely (and undesirable) that any decisions will be made at this meeting. You should have introductions to be sure everyone knows who is playing which roles (name tags might even be a good idea initially). The total meeting time cannot exceed 45 minutes (everybody is on a tight schedule).

Feel free to be creative with the case study. You can invent any reasonable kinds of relationships among team members that you wish. You can draw on any resources you need -- even outside of the class, if necessary. The overall success of this simulation as an educational tool largely rests in your hands. Good luck.

Session #1: Program Team Session Overview

This is the initial meeting and each player should concentrate on saying one or two major points which characterize their role (see individual scripts for more details). Try to state the points simply and clearly. You may have to make up some details in order to make your story realistic. That's OK, just be sure to take minutes of what you say so they might be included in the report to the Coordinator.

The general tone of the meeting should be cordial, but guarded. There is the potential for disagreement here on a number of levels, but this should be resisted if at all possible at this point (there will be time for that later!). In your Team Meeting before the Project Meeting, you should briefly develop an agenda and decide what major points you intend to make.

You should remember that the PD is the person in charge. You are there at the PD's request. When all else fails, the responsibility for managing the project falls on the PD's shoulders (after all, it is the PD's career that's on the line). You should also think about the team dynamics. Clearly, the PD and the MD are good friends. The MD is a bit of a "mentor" for the PD -- older, more experienced in research, and wanting the PD to succeed with the "Old School." The GO is a bit of an outsider -- an observer of sorts and will mainly introduce restrictions from the Federal perspective (either financial or methodological). The HA is likely to be at odds with the PA. In fact, the PA is likely to be at odds with all of the team (only the fact that the PA is a reasonable person prevents open warfare from breaking out).

You should also keep in mind your roles with respect to the Research Team. Remember that you are buying their services and, like any good consumers, you need to beware. However, you are stuck with them -- it would be too embarrassing to let them go and get other consultants after you've already assembled this prestigious group. You also need to keep in mind that you are trying get the best product possible at a reasonable price. The Research Team has no vested interest in keeping price down -- you do.

Session #1: Research Team Session Overview

This initial meeting is your first chance to get information about the project and to begin to assess the methodological options. You should approach this meeting as a "fact-finding" session. The Program Team is responsible for overseeing the meeting. At some point you should be given time to ask questions. Try to state your questions simply and clearly, and please try to keep them to only essential ones. You may have to make up some details or make some reasonable assumptions in order to make your questions realistic. That's OK, just be sure to jot down the essentials of anything you make up so it might be included in the report to the Coordinator.

The general tone of the meeting should be cordial, but guarded. There is the potential for disagreement here on a number of levels, but this should be resisted if at all possible at this point (there will be time for that later!). In your Team Meeting before the Project Meeting, you should briefly develop a sense of the major questions which you intend to ask. Whatever happens, you should realize that this is only the first meeting. Try not to commit yourself to anything at this point, even though you may be asked to give some idea of what kinds of options are available under various conditions. Ideally, you want to have an opportunity to discuss specifics in greater detail within your team after the Project Meeting.

You should remember that the CC is the ultimately the person in charge for your team. You are there because the CC recommended you to the PD. When all else fails, the responsibility for stating the Team's position rests with the CC (after all, it is the CCs career that's on the line).

You should also think about the team dynamics. Clearly, there is likely to be some disagreements between the SC (who sees everything as statistics) and the DC2 (who views validity issues as primary. Also, you've got a lot of strong, independent egos on this kind of collaborative team. The DC1 tends to be snobbish about the centrality of Cook and Campbell and wants to stick with the "Bible" (i.e., Cook and Campbell text) on most issues, whereas the DC2 is willing to entertain some newer ideas (the DC2 also accepts the general premises of the Cook and Campbell tradition, but is willing to part from it -- the DC2 would be a big fan of the Trochim text which extends much of the Cook and Campbell tradition and would also be interested in mixing qualitative and quantitative methods). The MC and SC tend to be rather narrow in focus -- both view their areas as of highest importance -- and tend to be the outsiders on this team. The rest of the dynamics you'll have to invent.

You should also keep in mind your roles with respect to the Program Team. Remember that they are buying your services and, like any good consumers, they will be concerned about what they are getting. However, you are stuck with them -- you've made a public professional commitment to assist on this project and it would be very embarrassing to back out now. You also need to keep in mind that your major goal should be to provide the very best methodological advice possible -- your competence as a researcher will be judged in part on the basis of how well this turns out. You have no vested interest in keeping price down at the expense of quality work -- the Program Team does.

Session #1: Project Director (PD)

Confidential

You probably have the most demanding role on your team. Ultimately, you have the responsibility to make decisions about the acceptability of any alternatives. But you have tremendous resources to draw upon! In effect, the Research team works for you. But, they are a fairly egotistical bunch and are going to require delicate handling on your part. Here are some suggestions for the first meeting.

First, assemble your team for the Team Meeting. Make sure they are introduced and say a few words about themselves. Tell them that the purpose of the Project Meeting is to introduce them to the Research team and to lay on the table the major methodological concerns that the Program Team has. Give each of your team members a chance to put some issues on the agenda. Decide how the meeting will be managed and who will take notes. You will chair the Project Meeting. Use your team to help set up the agenda. The only requirement is that you set aside enough time for the Research Team to ask questions.

Your major concerns tend to be broad ones:

- What kind of design should we use to assess the research questions?
- What are the major measurement issues/potential pitfalls?
- How big should the sample be?
- What are the major potential implementation problems?

Remember, this is going to be a major study conducted over a five year period and involving hundreds of persons and several hospitals. There are lots of potential issues which you can either raise or decide to settle on your own. For instance, you could raise the issue of whether you want to sample hospitals or you could simply decide that because there are few enough hospitals in the Design Consultant 2 (DC2), (notice I've never told anybody exactly how many there are) you are going to use all of them. You need to be prepared to make these decisions -- that is, you need to be ready to FAKE IT if no one knows what the facts are. However, before you make something up, you should always consult with your team -- they may have been secretly given some relevant facts!

One key question that is likely to come up concerns the two major outcomes and how you would like to measure them. At this point, you can tell the research team that you are looking into the existing literature and will have some potential measurement ideas for them at a future meeting.

Here's one secret just for you and the MD: only you and the MD know that you asked the MD to be at the meeting deliberately to play devil's advocate. The MD is supposed to play a real "hard-ass" medical researcher who believes that only randomized clinical trials (i.e., randomized experiments) can successfully tell whether a program makes any difference. Both you and the MD think that it might be impossible to actually implement a randomized experiment in this study, but you want the MD to advocate that as the most scientifically rigorous approach. You set this up in order to keep the Research team honest -- if they are going to recommend anything else, you want them to know that rigor is extremely important to you and to this study.

The outcome of this meeting should be to come up with a list of issues which need to be investigated by each team. Your team may have to get some more facts about the project for the Research Team to use. The Research Team will probably need to start digging into the methods literature to come up with some methodological choices and recommendations. Your job is to try to make sure everybody comes out of this meeting knowing what they have to do next -- and that everyone has a job.

One more thing -- you are the only person on either team who has the option of calling a conference with the Case Study Coordinator directly. If you really feel lost and want to consult with me only you may request it. Do so sparingly! Good Luck.

Session #1: Medical Director (MD)

Confidential

Your first job is to become an expert in randomized clinical trials or randomized experiments. First, you need to know that those two terms are essentially equivalent, but come from two different traditions -- "randomized clinical trials" is the language of the medical community (that's you) and "randomized experiments" tends to be the broader language of the social science community. To get a start on this, you should begin reading Chapter 8 of Cook and Campbell and Chapter 4 of Judd and Kenny. You should especially know that Chapter 8 of Cook and Campbell has a pro and con section. You should obviously be prepared to argue that this study has conditions which are conducive to randomized experiments and expect that others may argue that there are serious obstacles. If you want to get a real feel for the kind of strong position you might take, read the first three articles in the August 1985 issue of Evaluation Review (Volume 9, Number 4, pps. 387-440). This was a major statement by a prestigious group who are strong advocates for randomized experiments.

You and the PD are good friends. You also have a secret. The PD invited you to this first meeting specifically to play devil's advocate. The PD wants you to play the "hard ass" medical researcher type. You should be a strong advocate for randomized experiments as the best (and maybe even the only) way to achieve scientific rigor when addressing a causal hypothesis. You should feel free to suggest that a randomized experimental design might be the method of choice for this study. Also, feel free to act the pompous role of the one who has the "right" way to do things -- people who suggest alternative designs are not real scientists.

Don't feel like you have to be too pushy in this first meeting. Just make sure that you make the general point about the desirability of randomized experimental designs. Remember that you may have to compromise on this issue later in the case study if it appears that the prevailing judgement is against you. Also, give some thought to who will be your natural allies on this issue (both on your team and on the other one), and who will be likely to be opposed.

Session #1: Grants Officer (GO)

Confidential

You work for the National Institute on Drug Abuse in the Federal Government. As the Grant Officer, it is your responsibility to supervise the implementation of this grant. However, you are not an expert on the issue of cocaine treatment research -- that's why your agency gives grants to others instead of you. Remember, that is this grant turns out to be an embarrassment, it will reflect poorly on you and your agency. It is appropriate for you to state positions which represent NIDA thinking, but only in extreme emergencies can you force a position on the project.

The main perspective which you must take is that NIDA wants to have high quality research which will increase its visibility and credibility (and, consequently, its funding from Congress). You have to juggle the interests of the medical and research communities as well as of the patients (remember, even cocaine abusers have the right to vote). You should be a supporter of randomized experiments because they are generally recognized at NIDA (and throughout the medical and research communities) as the "strongest" research designs. However, you might be willing to consider some alternatives to randomized experiments as long as you're convinced they are scientifically credible (and won't embarrass the agency). Similarly, on measurement issues, you want to see high-quality measurement.

In general, you will tend to argue for the status quo in research methods. You don't want to do anything too wild or crazy or new because that might make too many waves.

To get a start on understanding your role, you should begin reading Chapter 8 of Cook and Campbell and Chapter 4 of Judd and Kenny. You should especially know that Chapter 8 of Cook and Campbell has a pro and con section. You should obviously be prepared to argue that NIDA believes that this study has conditions which are conducive to randomized experiments and expect that others may argue that there are serious obstacles. If you want to get a more detailed feeling for the kind of position you might take, read the first three articles in the August 1985 issue of Evaluation Review (Volume 9, Number 4, pps. 387-440). Especially note the two "comments" articles because they were written by Federal bureaucrats in a position similar to yours.

For this meeting, you might want to play it a bit conservatively. See who seems to be arguing which positions, gauge the political winds, and lend some verbal support to those who seem closest to your views.

Session #1: Hospital Administrator (HA)

Confidential

You obviously represent the interests of the hospitals in this study. You need to find out something about hospitals and the treatment of cocaine abuse. One thing you could do is interview or check with some of the people associated with the Sloan Health Administration program in the Department of Human Service Studies. Ask them what you might read to get an overview of some of the major issues which tend to be affecting hospital administration these days -- especially when it comes to drug abuse.

Here are some positions you might think of taking at this meeting. First, while you support the idea of this research, you cannot let it affect the "bottom line" -- if you start losing money, you will need to consider your options. Second, you (and all the hospitals in NortheastNet) are constantly in conflict with the third-party insurance companies who are increasingly infringing on your rights to control the course of treatment for your patients. You think that this might have a serious effect on the study, and you need to look into this further. Third, there is quite a variety in the 10 hospitals which make up NortheastNet. They differ in demographics, size, and styles of treatment (e.g., preference for inpatient or outpatient). However, you do think that you can get at least some of them to be willing to cooperate in this study.

Session #1: Patient Advocate (PA)

Confidential

You are probably the "outsider" on this team. The other four are all part of the medical establishment while you tend to be critical of it. Nevertheless, you do have one major ace up your sleeve. This study simply cannot go on if the patients become convinced that their rights are being neglected. You are present to help assure that this doesn't happen. You will do the best you can to be alert for potential threatening decisions -- decisions which might lead to harm for the patients.

You already know that the medical establishment would prefer to do a randomized experimental study for this project. However, you have serious reservations about that. In a randomized experimental study, each patient would be randomly assigned to either the inpatient or outpatient treatment. That means that no matter how sick they are, they could be assigned to either one! You think this would be wrong and potentially dangerous. You believe that patients should have a right to help decide what treatment they receive. Even though you are willing to admit that for research purposes, sometimes they must give up this right, you strongly disagree that this means they should be assigned into an inappropriate treatment. At the very least, you think that sicker patients should be assigned to the more intensive (inpatient) treatment and that outpatient treatment should be reserved for those who are less sick and more able to handle this.

You should state these general positions sometime during the meeting. Also, stick to your guns at this stage -- you may have to compromise later (you really have little control here), but you must remember that you are an advocate. You are fighting the "good cause" protecting the rights of the innocent patient. To get some idea of what you might be up against, you should begin reading Chapter 8 of Cook and Campbell and Chapter 4 of Judd and Kenny. You should especially know that Chapter 8 of Cook and Campbell has a pro and con section. You should obviously be prepared to argue the con side -- that there are serious obstacles to using randomized experiments -- and expect that others will argue the pro arguments. If you want to get a more detailed feeling for the kind of position they might take, read the first three articles in the August 1985 issue of Evaluation Review (Volume 9, Number 4, pps. 387-440). Also, you might want to look around for some literature which is very critical of the "scientistic, experimental, manipulative, intrusive" model of science. You are in a good position to be the advocate for more open, participative, qualitative, unobtrusive research methods (if you really have the energy, you might read some of the qualitative research community's criticism of quantitative, positivist, experimental research).

Session #1: Coordinating Consultant (CC)

Confidential

You probably have the most demanding role on your team. You not only have to know something about research -- you also have to have some management and leadership ability. But, you are not operating alone -- you have a whole team who are there to assist you. At this point, you should be concentrating on two major things. First, you have to keep your team focused on the idea of gathering information. They should not move too quickly to a decision on any issue before they have the basic facts that they need. You may have to become facile at putting off the program team. As specific methodological questions arise, you should say things like "We will look into that and get you some information at our next meeting." This is a skill that will stand you well throughout your career! You should also be keeping notes as these issues arise about who on your team should be responsible for addressing which issues.

The second thing you should do is to begin to cultivate a broad perspective on research methods. You are not a purist by training (after all, your went to Cornell's Program in Evaluation and Planning, a bastion of eclecticism). You might begin by finding something in the literature by Charles McClintock and Jennifer Greene on mixed methods. You might also read the first few readings in the Trochim text (e.g., Cordray, Mark, Shadish), all of which take a fairly broad-based view. Finally, you should also be reading the first few chapters of Cook and Campbell which lay the foundation of a "thoughtful" mainstream view.

You especially need to be aware of the dynamics of your team. Watch out for eventual internal bickering, especially about the quantitative-qualitative debate. The program team is largely coming from a medical tradition where qualitative methods are not as readily accepted as they are in the social sciences. If your team members emphasize the qualitative stuff too much, you run the danger of losing considerable credibility with the program team. Encourage your more qualitatively minded individuals to think of sensible ways to interweave those methods with more traditional quantitative techniques -- again, the mixed methods literature should help.

During the first meeting, concentrate on getting the facts you need, keeping your team in line and looking professional and credible.

Session #1: Design Consultant 1 (DC1)

Confidential

You are going to have to become a quick expert on quasi-experimental designs. You should immediately begin reading Cook and Campbell's 3rd and 5th chapters and chapters 5, 6 and 7 of Judd and Kenny. A good quasi-experimentalist is always walking a bit of a tightrope. Most methodologists would argue that the "strongest" designs are randomized or true experimental ones. However, in applied social research these are often difficult or impossible to implement well. On the other hand, if we give up all attempts at control, we are likely to have a study which has little or no internal validity, and consequently can't answer the program evaluation question with any confidence. You argue for a middle ground. We should have as much control as the social setting will allow. You don't think the the randomized experiment types are realistic and you believe the nonexperimental types have given up prematurely.

You should know that the discussion is probably going to begin to focus very early on the desirability of using a randomized experimental design. You might want to look at the last chapter of Cook and Campbell to see what some of the pros and cons are. You think a simple randomized design would be unacceptable for this cocaine study, because it would mean that some of the sickest patients would (by the luck of the assignment) be assigned to outpatient treatment, but some of the more traditional medical people are likely to push for one because they view it as the most rigorous approach. In your reading, concentrate especially on the regression-discontinuity design as a strong potential alternative to randomized experiments in this cocaine study. Figure out why it would be a good option. You might want to look at Trochim's paper on the regression-discontinuity design in health research to get a clearer idea. During this meeting you can allow yourself to be a little aggressive, especially if the program team starts pushing hard for a randomized study. Also, it might be a good idea for you to begin to identify who on your team and on the program team would be your natural allies on this issue.

Session #1: Design Consultant 2 (DC2)

Confidential

You are going to be the resident expert on validity issues. That means that you should quickly begin to read chapter 2 of Cook and Campbell and chapter 3 of Judd and Kenny. For a broader (and more recent) perspective, you should read Mel Mark's chapter in the Trochim volume. You have a lot in common with the DC1. However, it is important to understand where you would differ. The DC1 will tend to see traditional quasi-experimental designs as preferable alternatives in most settings. You are a little more up to date. You know from reading Cordray's chapter in the Trochim text that experiments and quasi-experiments haven't performed all that well in real social settings. In fact, Cordray's position (along with Mark's) would be a good general stance for you to take. You are not a methodological purist -- you would tend to be much more eclectic than DC1. You always believe that it should be validity questions which drive methodological choices. Make sure that you can identify the different validity types and when the project meetings occur, try to classify different issues which arise in terms of their validity components.

You are also likely to be the strongest ally of the CC on your team. The CC also tends to be eclectic and broad-minded. You may have to help the CC to keep your team from internal bickering on which methodologies to recommend.

At the first meeting you can take a philosophical pose. If people start disagreeing about methods, you can calmly interject that whatever methods are ultimately chosen (and they don't have to be decided upon this early) your main concern will be (and theirs should be) to ensure the greatest level of validity for this study.

Session #1: Measurement Consultant (MC)

Confidential

You are the measurement expert on your team so you better be sure you know something about measurement. You might start by reading any introductory research methods books of the topic of reliability of measures and how we establish this. You should also read anything you can get your hands on about construct validity of measures. There are appropriate sections on this in chapter 3 in Judd and Kenny and chapter 2 of Cook and Campbell. You should also pick up the classic paper by Campbell and Fiske on the multitrait-multimethod matrix approach to construct validity. You will also need to know something about scaling. Again, standard research methods texts would give you some simple introduction to unidimensional scaling methods.

You are also the only one on your team that will know much about sampling. In addition to standard research methods texts on this, you should read about external validity in Judd and Kenny and in Cook and Campbell. There is probably not going to be any opportunity to do any fancy sampling in this study. In fact, you already know from the study abstract that they are going to sample from diagnosed patients at NortheastNet hospitals.

At this first meeting, your major purpose should be to try to get some basic information. You want to know if the program team has any idea how they are going to measure the two major outcome constructs (i.e., drug use and psychosocial functioning). You might suggest that they should think about defining what these constructs mean and look around for some possible existing measures which would be relevant. Remember, you like to be precise and you expect that they would have already thought this major issue through.

Session #1: Statistical Consultant (SC)

Confidential

There is really not a lot for you to do at this first meeting except sit back and enjoy the discussion. You need to begin to read about the statistical analyses which are used for different designs. You might start taking notes on what types of analyses are associated with what types of designs. Try to become more comfortable about talking in analysis terms, using phrases like ANOVA and ANCOVA, and reliability-corrected Analysis of Covariance (ANCOVA). Look at Judd and Kenny, chapters 4, 5, and 6 to see what models they would use for randomized experiments, regression-discontinuity designs and nonequivalent group designs, respectively. Also look at chapters 4 and 6 (skim this one) in Cook and Campbell to get their views. You are going to need to become familiar with the general linear model equation outlined in Chapter 2 of Judd and Kenny. Finally, if you get this far, begin reading the articles by Rindskopf and Reichart in the Trochim volume.

About the only thing you might add to the first meeting is the statistician's view that randomized experiments are more straightforward and easy to analyze than quasi-experiments. You could explain that the more you give up control (that is, the more you move away from randomized assignment) the more complex the statistics will become and the less definitive the conclusions. This being said, you still don't mind the challenge of analyzing a more complex design (in fact, you might actually welcome it).

Session #1: Cocaine Treatment Study

Session #2: Program Group Overview

This is going to be a very busy meeting for your team because you have a lot of information to present to the research team. Some of the information is imbedded in your scripts which you should read very carefully. Some of it is in documents which you will be giving to the research team. You should also read these documents carefully. Here's a list of documents to be given to the research group and who will present each:

1. Excerpts from the original research proposal (PD)
2. NortheastNet Standards for admissions and treatment (HA)
3. Hospital Sites Descriptive Information, Tables 1-3 (MD)
4. Definitions of Disorders/Diagnostic Categories (MD)
5. Symptoms Checklist 90 (SCL90) documentation (PD)
6. Treatment Cutbacks, Legal Ramifications Concern Labor (PA)

There are two major things you should focus on in this session:

1. Present your material as clearly as you can. There's an enormous amount of stuff here and you're responsible for getting it across.

2. Insist that the research team come back with a preliminary design report at the next session. This preliminary design report should focus on the design options which they think are reasonable for the project, and which option they believe is preferable.

Give them some guidelines for the report (e.g., keep it short, simple, etc.). You can see that although you are doing most of the presenting this time, they will carry the brunt next time.

Let me also give you some advice on dealing with requests for information from the research team. In this session, you are giving them the bulk of what you know and have data on. This should pretty much be enough info for them to give you some reasonable methodological options. They are likely to want to stall for time. Beginning with this session, you should begin to get more and more impatient with their requests for details -- unless they can convince you that they need that information. When they do, try to give them the simplest answer you can. For instance, if they ask you about site differences, tell them that it is your belief that there aren't any significant site differences. If they ask about population characteristics, tell them that they are typical of cities of this type. Try to focus them on their task -- to help advise you. You will not be able to answer every little question they might raise. Remember, they were hired as research consultants. The nature of the treatment program is really none of their business. Actually, it's not really your business either -- it's the responsibility of the hospitals. Furthermore, although they might like to ask lots of questions about the make-up of the metropolitan area, make-up of the population of interest, and make-up of the intended sample, these things are essentially outside of their ability to influence -- they have already been chosen and are fixed for this study. They are limiting factors, but you are well aware of them and realize that this study will not answer all questions for all cocaine abusers in all locations in the U.S. -- subsequent research would be needed to see whether results obtained here are extendable to other contexts. This is understood by you and was perfectly reasonable in the view of NIDA. In other words, while they might be interested in some details about city, population or sample, before they request any more info about these they better make sure that it is relevant to their need to determine the research methods which are appropriate -- you will get increasingly tired of their asking for information which you see as tangential to the issue for which they were hired.

Session #2: Research Group Overview

This is likely to be a fairly easy meeting for you. The program group is responsible for providing you with the information you requested in the first session. Expect that they will have lots to say. Also, expect that they may not be able to answer every little question you might raise. Remember, you were hired as research consultants. The nature of the treatment program is really none of your business. Actually, it's not really the program group's business either -- it's the responsibility of the hospitals. Furthermore, although you might like to ask lots of questions about the make-up of the metropolitan area, make-up of the population of interest, and make-up of the intended sample, these things are essentially outside of your ability to influence -- they have already been chosen and are fixed for this study. They are limiting factors, but the program team is well aware of them and realizes that this study will not answer all questions for all cocaine abusers in all locations in the U.S. -- subsequent research would be needed to see whether results obtained here are extendable to other contexts. This is understood by the program team and was perfectly reasonable in the view of NIDA. In other words, while you might be interested in some details about city, population or sample, before you request any info about these you better make sure that it is relevant to your need to determine the research methods which are appropriate -- the program team may get tired of your asking for information which they see as tangential to the issue for which you were hired.

Session #2: Project Director (PD)

Confidential

You have lots of information to convey in this session and so does the rest of your team. Try to keep the meeting organized and on task. You are responsible for the two major tasks outlined in the Program Group Overview -- make sure they both get covered.

You really have no confidential stuff this session. You probably need to present everything detailed below. However, keep in mind the roles of your team members -- the first session roles still apply here. For instance, you still have a secret agreement with the MD that the MD will play devil's advocate for randomized experimental designs.

Try not to let the research team request too much additional information in this session. Tell them that you think the documents you are handing them and the info you are providing them should answer most of their questions. Insist that this should be enough information for them to come back next time with a preliminary report (oral is OK!) on research design options and their preferred choice.

At some point in this session you must give the research team a copy of

- Excerpts from the original research proposal (PD)
- Symptoms Checklist 90 (SCL90) documentation (PD)

and a brief description of what they contain. Clearly, the research proposal excerpts are crucial. You should tell them that you only gave them the sections that were relevant for their task and that in order to preserve the confidentiality of the program team and affiliated persons, you couldn't give them certain sections (e.g., budget) and you had to "black out" some details. You should inform them that, of course, they realize that this is typical when dealing with consultants on research projects.

Here are some of the points I would like you to make during this session (in addition to handing out documents):

Hypotheses

Remind them that the central hypothesis of the study is:

> Inpatient treatment for persons with more severe cocaine dependence and psychosocial impairment results in better outcomes than outpatient treatment.

and refer them to the excerpt from the proposal.

We have no interest in examining site differences in the initial analyses. We intend to look only at overall treatment effects across sites. At some later date, we may get back to the data to look at site issues, but that should not concern us now.

Prior Research

All of the prior research that we have is documented in the excerpts from the research proposal. In addition, the recent literature on alcohol treatment effectiveness includes a meta-evaluation of about twenty different studies comparing inpatient versus outpatient treatment of alcohol abuse. The bottom line was that it was clear that there was no significant difference in effectiveness between the two treatments. Consequently, because inpatient treatment is so much more expensive, outpatient treatment is significantly better in terms of cost effectiveness and cost benefit figures. If I can find my copy of this article, I'll get it to you, but you probably don't need any more than I just told you.

Sample

The study will utilize all patients at the four participating hospitals who meet treatment criteria at any time during the study's 24 month recruitment period. The sample is limited to only those who are in the work force because they make up the vast proportion of clients at NortheastNet Hospitals and because they are in a position to pay for service, or have insurance to cover it. If significant effects are found in this study, it is likely that it will be desirable to replicate it on other, non-working samples.

Outcomes to be Measured

Drug Use

a. slips (single occurrences of cocaine use)
b. relapse to cocaine
c. relapse to any other drugs

Level of Psychosocial Functioning

a. medical
b. legal
c. employment
d. alcohol and drug use
e. psychopathology
f. family, including social

Details about the measures we will use are provided in the excerpts from the proposal. These are all standard measurement constructs for this type of research and have been used in other studies. We have had prior research experience with all of the measures except for the Symptoms Checklist 90 (SCL90). We would especially like the research team to concentrate on that measure and address the following:

1. What is the reliability of this measure?
2. What is the validity of this measure?

I'm giving you a copy of the documentation which came with the measure. It includes a copy of the complete measure and accompanying information. Please report back to us at a future time (probably not the next session) on what you find out about the measure.

Design

We do not have any research design currently chosen. We expect that a randomized experiment would be the strongest method available to answer the research questions, but we have some concerns about the ethics of randomly assigning persons to treatments and about the degree to which hospital staff would be willing to implement this. For instance, we are concerned that even if we assign a person at random to receive outpatient treatment, if the hospital staff feels that person is sick enough to warrant more intensive inpatient treatment, they may find ways to move the person to that condition. This would jeopardize our results. We are essentially asking the research team to advise us on either how to control these kinds of problems or on design alternatives which still meet standards of rigor.

Data

Some data may be made available to you at a later date. We are hiring program staff who will do all preliminary and descriptive data analysis. What we will need your help on is the data to analyze the outcomes to assess the major research questions. We are likely to give you the relevant outcome data as soon as we have enough to make some preliminary analyses reasonable.

Staffing

You should know that we are in the process of hiring staff for this project. We will have a program staff member on each site, in addition to central staff responsible for data management, preliminary data analysis, project implementation, and so on. For now, all direct contacts with the four participating sites are through the HA.

Budget

On the issue of budget, you should not disclose to the research team how big the project budget is. You should simply inform them that you believe that you have more than sufficient funding to do a high-quality job and that their (the research team's) role is to advise you on the best methodology to us to answer the research questions. You don't have to be nasty about this -- just keep the research team focused on their job and tell them that funding is your responsibility.

Session #2: Medical Director (MD)

Confidential

You have two documents to hand out at this meeting and you should be prepared to give a short description of each. They are:

- Hospital Sites Descriptive Information, Tables 1-3 (MD)
- Definitions of Disorders/Diagnostic Categories (MD)

For instance, you might say something like: "I have made more detailed information about the definitions of "substance dependency" and "substance abuse" available in the accompanying handouts under the heading Definitions of Disorders and Diagnostic Criteria. I also have made available some information about the demographics of inpatients versus outpatients for three of the four sites (the fourth site did not have data readily available). This is labeled Tables 1 through 3 in the handout."

You should remember your role from last meeting. Remember that you and the PD still have an agreement that you will play devil's advocate for randomized experimental designs. It's not likely that research designs will come up at today's session, but if they do, you should be prepared to reiterate your position. Be tough!

Session #2: Grant Officer (GO)

Confidential

Your basic role in this meeting is again to provide information about the Federal perspective. One of the questions raised concerned concerns the motivation for this study. You should find a way to work into the conversation this week the response that the study was originally motivated through the Federal government. Try something along these lines (please paraphrase this in your own words!):

> "Cocaine abuse is increasingly recognized as an important issue by Congress and the nation as a whole and treatment of cocaine is not very well understood. The National Institute for Drug Abuse (NIDA) has the responsibility to implement a program of research to address timely issues of concern such as this one. NIDA let out a Request For Proposals (RFP) for research assessing the relative effectiveness and cost effectiveness of cocaine treatment. The PD submitted a proposal which is one of several in this topic area which have been funded nationwide."

A second question -- and one that is likely to recur throughout this study -- concerns what NIDAs guidelines are. You can tell them that due to the large number and variety of studies which NIDA sponsors, there are no written, off-the-shelf guidelines. You should stress that the reason you are there in person is to be able to insure that whatever is done meets acceptable standards for high-quality research. What is "high-quality" research? Refer them to Cook & Campbell, Judd & Kenny, and the Trochim volume as three sources for determining what high quality research is!

You should also mention that there are some other issues which have become more important and prevalent over the past year and which NIDA is considered might negatively affect this study because they make it harder for the program team to control which treatment a person is assigned to. Number 4 should be self-explanatory. If they ask what the others are, see if anybody else at the session has any idea. If not, just tell them that you're not sure you want to define them -- you only got this list from NIDA today. Don't let yourself get stuck finding out what these things are. Suggest that the program team and research team should find some way to check out what they are and what their implications might be.

1. Managed health care and how it will affect treatment assignments and length of treatment.

2. Employee Assistance Programs (EAPs)

3. Insurance coverage

4. Patient program preference.

5. The "day treatment" alternative

Session #2: Hospital Administrator (HA)

Confidential

You have one document to present this session:

- NortheastNet Standards for admissions and treatment (HA)

Tell them that this is a draft document (the final is in the works). Also, at some time during the session, work in the following material:

There are 4 hospitals (of the ten in NortheastNet) which are willing to participate (the others were not necessarily against the study but did not wish to participate because they didn't offer one or both treatments, or they didn't want to spare the resources which participation might involve), each with both an inpatient and outpatient program. Geographically, there is one site from each of the four major sectors/quadrants of the city. We really do not have any data on the numbers and types of alternative treatment programs which are available. In fact, many of these are informal, poorly documented or parts of other kinds of programs which fall under the jurisdiction of differing Federal, State and Local agencies. It would be very difficult to get comprehensive information on available treatment alternatives. All treatment sites are private, not-for-profit. We have no specific information about the funding of each site's treatment units at this time. Obviously, we will have to negotiate with each site to make available the necessary financial data for any cost-related hypotheses. We also have no specific data on the staffing levels of all four sites, although we expect that per patient rates are comparable because they all follow the same treatment protocols. All patients/clients have medical insurance/coverage or are self pay. Although treatment programs may differ somewhat from site to site, NortheastNet hospitals have expended considerable effort in developing standards which will insure a certain amount of comparability across hospital programs. All four use central intake procedures (i.e., not separate intake procedures for inpatient and outpatient). All four have separate detox programs. All four are investigating the possibilities of developing a day treatment program. All sites are urban. There is broad heterogeneity in the characteristics of the populations served at any hospital, but across hospitals, the populations are essentially very similar in make-up. In general, the patient populations are similar in characteristics to populations of most cities in typical U.S. northeastern cities (e.g., Buffalo, Syracuse, Worcester, are examples). Here is all of the site-specific data we have available for the four participating hospital sites:

Site 1 (Northside Hospital)

Capacity: 40 inpatient(IP) slots; 30 outpatient(OP)
On average, 41 IP, 17 OP admits per month
approx. 23 cocaine admits/month (40% of all patients)

Site 2 (Southside Hospital)

Capacity: 28 inpatient(IP) slots; 72 outpatient(OP)
On average, 24 IP, 14 OP admits per month
approx. 13 cocaine admits/month (32% of all patients)

Site 3 (Eastside Hospital)

Capacity: 36 inpatient(IP) slots; 50 outpatient(OP)
On average, 35 IP, 3 OP admits per month
approx. 7 cocaine admits/month (21% of all patients)

Site 4 (Westside Hospital)

Capacity:	39 inpatient(IP) slots; 25 outpatient(OP) (No average monthly admissions data available) approx. 5-15 cocaine admits/month

In addition, I am providing you with excerpts from a document which describes NortheastNet's currently agreed upon standards for treatment (for adolescents only), admission screening criteria, and treatment expectations. This should give you some idea of the types of standardization which we use.

Session #2: Patient Advocate (PA)

Confidential

You may throw a very small wrench into the works this session (the following is very confidential). Your main role in this session will be to raise questions about whether this project is likely to work out the way it's planned (no matter what the plan is). One of your main points has to be that the typical context of cocaine treatment is just not very conducive to doing good research. You should point out that there are a number of issues which are likely to affect even something as basic as whether the program staff will have any control over the assignment of clients to treatments. Many of these issues are likely to be raised by others on your team. Whether they're raised by you or by others, you should stress that you think they will jeopardize any research design they might come up with. The issues are:

1. Managed health care and how it will affect treatment assignments and length of treatment.

2. Employee Assistance Programs (EAPs)

3. Insurance coverage

4. Patient program preference.

5. The "day treatment" alternative

All of these issues are related to treatment assignment. Increasingly, the type of treatment which one receives is determined not by the physician and patient on the basis of clinical judgement, but rather by third parties -- insurance agencies, EAPs, managed health care requirements, and so on. Learn a little bit about these issues and be prepared to raise them if no one else does. To show more concretely how lots of outside forces are increasingly impinging on the decision regarding type of treatment provided for a patient, give the research team the article "Treatment cutbacks, legal ramifications concern labor." Essentially, it lends support to your contention that this is going to be an increasingly difficult environment within which to attempt "controlled" research.

In addition, you might want to mention that cocaine treatment programs -- especially outpatient ones -- lead to fairly high drop-out rates. You might want to ask the research group whether this would make a difference (it certainly should, especially if there are differentially higher drop-outs from one group than from the other). Also, don;t forget your role from last session. Be on the alert for issues and ideas which might not be fair or beneficial for the clients.

Session #2: Consulting Coordinator (CC)

Confidential

This session, you are likely to be doing a lot of listening. The program group is going to be giving you and your team a lot of information that you requested during the first session. In your pre-session meeting you should organize your team to be ready to receive this information -- you can't assume that everything that's important is already on paper -- they may have important things to say and if you don't write them down, you might miss them.

You need to keep your group focused on their major roles -- advising the program team on research methods for this study. They may have a tendency to want to get into lots of details which are interesting and perhaps relevant but which aren't central to their goals -- it is your job to keep them on track. In the very near future, you are probably going to have to begin to give them advice -- you need to remind your team that they haven't got forever to figure this all out -- they will have to give it their best shot even if they aren't fully prepared.

The program team doesn't need methodological advice on absolutely every little nuance about research -- they have considerable experience implementing successful research projects prior to this one. You need to realize that their first and major priority is to settle on an overall research design. Once that is decided, there are many other issues that will begin to fall into place around it. You're especially going to have to push your two design specialists (and yourself) to lay out the range of reasonable design options and to pick one that seems most reasonable to you.

Remember that you are working for the program team. If they make a reasonable request of you, you are really obliged to try to accommodate them. Make sure they are clear about anything they might want from you or your team.

One more thing. You should recognize that at this point in the case study, your two design consultants have a lot more to do that the MC or SC has. Part of your role is to make sure that there is some equitability across team members. Depending on how things go, you might want to suggest that if they have no pressing issues they may want to help others on the team who do. Or, you might be able to think of another way to utilize this latent person-power at this point.

Session #2: Design Consultant 1 (DC1)

Confidential

You probably won't have much to do this meeting except take in information that the program team supplies. By now, you should already know something about the regression-discontinuity design. You should think of the major types of designs as being on a continuum from most rigorous to most implementable. On one extreme (rigorous) are all of the randomized experimental designs -- they are generally preferred by methodologists, but are difficult to implement for a variety of reasons. On the other extreme (implementable) are the quasi-experimental designs, especially the pretest-posttest nonequivalent group designs. These are easy to implement, but are not very rigorous because there is always the possibility that differences between the two groups on the posttest are due to initial differences between groups (a selection threat to internal validity). In the middle is the regression-discontinuity design which is a very special type of quasi-experiment which is not very susceptible to selection threats (you need to investigate why this is so). Finally, there are even finer gradations. For instance, a very strong compromise design is a regression-discontinuity design which has a cutoff interval instead of a single cutoff point. Persons scoring on one side of the interval on the preprogram measure are assigned to one group; those scoring on the other side are assigned to the other group; and those falling within the interval are randomly assigned. This is an example of coupling a randomized experiment with a regression-discontinuity design. It has most of the advantages of both a randomized and a regression-discontinuity design and has very few disadvantages (except that it may be difficult to explain or sell to the program team and it has never actually been used in a real research context) -- see Trochim's regression-discontinuity paper for more details on this one and other variations. Keep in mind that you are likely to need to provide the program team with a range of reasonable options in the very near future. Start figuring out what they are and getting ready to present them clearly and succinctly.

Session #2: Design Consultant 2 (DC2)

Confidential

One of the major issues that you need to be aware of is the general issue of internal validity. This project is not very concerned about external validity or generalizability, and that's probably OK. In this kind of research, a single study would never be relied upon to answer so complex a question. So, both the program team and NIDA are likely to be interested in doing a good job in assessing whether there are treatment differences in this setting and with these particular types of cocaine abusers, rather than being able to generalize across the full range of possible settings and populations.

That being said, if they don't have great external validity that is no big deal -- other studies will help to establish generalizability. But, if they don;t have external validity, they must have internal validity or they'll wind up with absolutely nothing. Consequently, you need to read the relevant sections in Cook & Campbell, and Judd & Kenny on internal validity. You should especially concentrate on understanding the issue of selection bias. Note that even though a randomized experiment is not susceptible to selection bias if it is correctly carried out, it may not be reasonable to expect that it can be implemented well in this or most other situations. If we have differential drop-outs in the two treatment groups (aren't we likely to have more dropouts from the outpatients than the inpatients???) this almost certainly introduces a selection bias. Thus, we might want to move to a design which is strong against threats to internal validity, but which doesn't involve inappropriate assignment to treatments for the sake of randomness. That is, we might want a design where person who are sicker are assigned to inpatient while those who are better off could be put in outpatient.

Start encouraging everyone to begin thinking in terms of "compromise" designs or strategies which are both realistic and as rigorous as we might expect.

Session #2: Measurement Consultant (MC)

Confidential

You really won't have too much to do this session except listen to what the program group has to say. However, you should continue reading up on some central measurement topics such as reliability, validity, and scaling. In this case study, we are not going to be able to get into all of the nuances of all of the possible measures that are involved -- there's just not enough time. Look for signals for others about what aspects of measurement they want you to focus on -- let them tell you what they need. Remember that you are acting as a consultant to the program team. They already have considerable experience in implementing research of this type and feel confident about many measurement issues -- they are likely to ask for your help on specific issues which are puzzling or new to them.

Session #2: Statistical Consultant (SC)

Confidential

You really aren't going to have a lot to do during this meeting except listen to the information which the program group provides. You should know a few things however. The type of design which is ultimately chosen can either make your life easier or harder -- therefore you have some vested interest in what is decided. For instance, a randomized experiment is very easy to analyze and there are countless examples of such analyses in stat books and in statistical software manuals. The regression-discontinuity design is a bit more difficult. Most other quasi-experimental designs can become a bit nightmarish. Also, the more esoteric the design (and the less frequently it's been used) the more difficult the analysis is likely to be. You should be aware of this and make your team aware of it because you may be given some data later in the case study and you may have to take a crack at analyzing it!

In any event, if you have never played with a statistical software package, now might be the time to begin looking into it. Ask your other team members what they have experience with. Try to do some simple simulations of some of the major research designs. I have included a copy of a paper by Trochim & Davis which introduces the idea of statistical simulations and would give you an opportunity to "try out" analyses on data where you already know what the correct answer should be -- a good skill to acquire!

Session #3: The Cocaine Treatment Study

Overview of Session

At this point in the Cocaine Study, the major issue is choosing a general research design. Right now this project is a little bit like a juggler with a lot of balls in the air at the same time. Once you make some decisions, a lot of other things will begin to fall in place.

You should all also recognize some of the limitations to what we will be able to do in these simulated case studies. You aren't going to be able to solve every little detail or nuance. In fact, there are going to be lots of measurement, sampling and program delivery issues you won't even be able to address and that will probably be frustrating. However, because the major purpose of these exercises is to teach you about research design and validity, we have to cut some of the detail out. You should also know, if you don't already, that even in real life consulting situations one often gets the feeling of making decisions on the basis of incomplete or partial information. You gather as much information as you can and then, when a decision has to be made, you make the best decision you can given your knowledge. That's reality.

Try to remember your roles as we progress through these meetings and try to put yourself into a realistic professional frame of mind about this stuff. What would a professional do in your situation? How would they handle the group dynamics? How would they deal with the decision-making process? What would a professional do if the others in a group went against their opinion?

Although there may (and probably should) be some contentious, spirited debate about options, in the end, it is to everyone's advantage to reach some degree of consensus about the compromises which are made in choosing a design.

You should also know that there really is no correct answer here. Each answer has different advantages and disadvantages. By choosing a particular design, you are picking specific battles that you will have to wage later in order to get the most from that design. Subsequent scripts will be more tailored to whatever design you choose and will illustrate some of these trade-offs well.

Session #3: Project Director (PD)

Confidential

At the next Project meeting, the Research team should be prepared to lay out some options for research designs for this project. You should push them to give you several options and then to prioritize them and recommend one that they think may be best. You will then want to discuss the options with your team and make some decision. If you feel there is consensus on your team about which design to use, and you get some idea from the Research team that that would be their choice, then you may not have much difficulty in making this decision.

But what if there are disagreements, either within your team or between teams? You must remember that ultimately this is your project. It is your career that is on the line. Like any good leader, you need to get advice from lots of sources, but at some point you may have to make the tough decisions. Remember who your friends are. The MD is your closest ally and someone who's advice you trust. But you may even have to go against the MDs choice if you feel that's appropriate. Remember also that the GO supports you and wants to see a good project done (although the GO will tend to be rather conservative and unimaginative). The HA also supports the project, but has lots of other factors to be preoccupied with. Use the HA to help negotiate with third party insurers and EAPs if that is needed -- the HA has the most direct contact with that crowd.

Try not to let things get out of hand in the discussion on design. The PA especially tends to rant and rave about patients' rights, but you should know that the PA was glad to be incuded as an insider in this project (they usually aren't) and would probably not want to lose that opportunity. Essentially, the PA can cause you trouble, but is not likely to want to leave the project just because a randomized experiment is the design choice (if it is). Try to manage all of these varied interests, but just remember that you are in a very strong position here -- you're already funded and unless you do something really outrageous you won't lose your core support (the MD, HA and GO).

As always, you should start the meeting, and you should ultimately control it. The Research team should be ready to report back to you this time on research design options, and perhaps on measurment (the SCL90) and maybe other things as well. The design choice issue is your most important priority. If you have time to get to anything else, that's OK, but if you don't, at least do a good job on design.

By the way, you know from your own reading that there is some possibility that the Research team may talk about a regression-discontinuity design option. If they do, you should know what options you have for coming up with a variable on which a cutoff assignment rule can be based. You have several choices. First (and maybe best) if it looks like this is the design you'll use, you might suggest that you will develop your own assignment measure for the project. Ask the MD to help. (You won't actually have to design a measure for this simulation -- just say that you will). The measure will be a series of ratings performed by a physician and an intake worker, and perhaps one or two others, regarding the severity of cocaine abuse. The ratings would be added to the intake procedures. The ratings will be summed for each rater and these total scores averaged to get the assignment measure. The cutoff point will be chosen based on a brief pilot testing of the instrument on current cocaine patients (inpatient and outpatient) in study hospitals. Your alternative option would be that the total score from one of the current intake measures be used. Probably the SCL90 is OK for this.

Good luck at this meeting...

Session #3: Medical Director (MD)

Confidential

Things are going to come to a head soon on the issue of research design, so I hope you've done your reading and are ready to make your case. You want to see a randomized experimental design. You're convinced it's do-able and that it represents the "Cadillac" of designs (you may not want to push this analogy too far given how crummy Cadillac has gotten!). You will push for this as far as you can. Remember how arrogant you can be when it suits your purpose! Anyone who recommends less than a randomized design must have gone to an inferior school! They can't possibly know science! Etc., etc.

In the end though, you have to remember that you are a friend to the PD. You hate to see the PD put in an impossible position on this research design stuff. At the last possible moment, after using all your powers of pursuasion, if the PD is in a bind, you may want to relent and provide some room for compromise. Of course, if you're successful in your arguments, things may never get to the point of compromise.

If a compromise seems essential, you should ask whether it would be possible to retain random assignment at least for some of the sample. That is, is it legitimate to have a hybrid design which uses random assignment for some cases and some other method (you couldn't care less which other one as long as some of the cases are randomly asigned to inpatient-outpatient) to assign the rest?

See if the design team has any thoughts on these possibilities -- but don't bring them up until you've given up on a pure randomized experimental design first.

Session #3: Grant Officer (GO)

Confidential

You are goint to be a major trouble-maker during this next session. Why? Because you just got notice from your superiors at NIDA that the National Advisory Committee to NIDA has been asked by the Director to do an immediate review of research designs for all funded projects as part of a larger National Science Foundation study of quality of current research. You're really not sure about all the details (after all, you're not in charge of NIDA) but from what you've heard, there are several U.S. Senators who are raising hell about poor quality research and how it is a waste of taxpayer's funds -- especially a concern right now because it's budget time and there's a big deficit.

So, you've been instructed to find out immediately what the research designs are for all of the projects you oversee and report these back to NIDA. Any currently approved projects (like the Cocaine Study) which fail to report on this this week will be considered in violation of legitimate reporting requirements and their funding will be in jeopardy!!!

You're first reaction on hearing this is to immediately contact the PD -- do it right now, before the next session. You have to give the PD some warning that a design decision must be made at the next meeting!

Again, remember that you aren't too concerned about what design is chosen as long as it is high quality.

Your role at the meeting should be to make sure that they make a decision. Most likely they aren't going to feel all that comfortable doing so right now, but you should emphasize that they really have no choice if they want the project to continue.

You need to report two things to NIDA. First, you need to tell them the exact name of the research design which was chosen. Examples are: a pretest-posttest two-group randomized experimental design, or a regression-discontinuity design with a cutoff interval with a two group nonequivalent group design within the interval. Second, you need to depict this design in design notation (using Xs and Os and whatever else is needed). **Do not leave this meeting without these two things.**

You should also feel free to help them make the decision. You know a great deal about research design from your experience in managing projects. Feel free to add your own thoughts.

Finally, you should remember that you and NIDA are not particularly into taking risks. If it looks like the research design they are thinking of choosing is not one of the "big three" (i.e., randomized experiment, regression-discontinuity, or nonequivalent group design), all of which are widely known and accepted, you should express some concern. Any other design they come up with is likely to be a hybrid or combination of those big three and probably has never been used before in research. Do you, they and NIDA really want to go out on a limb trying some new, untested, design? It better be a good one.....

Session #3: Hospital Administrator (HA)

Confidential

One of the big problems you have right now is dealing with the EAPs and the insurance companies. They are increasingly taking control of treatment decisions. That is, they review the patient's status and decide whether they are willing to fund the treatment. If they don't think the treatment is appropriate, they simply will not pay. This is obviously going to be a big problem for the Cocaine Study because the higher-quality designs will require some control over assignment.

You have a couple of ideas however. You know that in the metropolitan area, probably 90% of all of the people who use third party payment programs fall into maybe 10 to 15 separate third party programs. You personally know very well the Director of the Health Insurance Consortium (HIC) for your metropolitan area. HIC is a group which meets monthly and has representatives from all the major third party insurance companies and EAPs. You spoke with him on the phone recently and told him about the study and he seemed genuinely interested in it. After all, it is in their interest to know whether the more expensive inpatient cocaine program is worth paying for, and for what types of patients.

Although you didn't ask him explicitly on the phone, you think that you and the PD might approach the consortium and ask them whether they would be willing to let the Cocaine Study control the assignment to treatment for eleigible clients in their programs.

Essentially, you want to know whether that might help in terms of research design. What would the study do if some bout not all of the insurers were willing to give up control of treatment assignment??? Could you just use patients from cooperating insurers?

A few other things you should know. Remember who you are in this simulation. You want to participate in this study because you think it's important. But you cannot in good conscience continue your involvement if it is going to become too much hassle for you or the other participants in NortheastNet. You and your member hospitals can't afford to lose money and can't appear to get involved in a boondoggle or a conflict with insurance companies. You don't need any bad publicity. What you do need is a nice high-quality study which you can say puts your group at the cutting edge of Cocaine Treatment (think of the advertising implications!). You want a research method for this study which will be consistent with current treatment procedures already in place at the hospitals.

Session #3: Patient Advocate (PA)

Confidential

Things may be starting to happen very fast! You have to be on the watch especially now. In the next few sessions it is very likely that a research design decision will have to be made. If it seems they are going to choose a simple randomized experimental design you should "scream bloody murder"! That is inappropriate clinically and denies the right of the client to participate in treatment assignment decisions. Similarly, a regression-discontinuity design also gives the client no choice, although it at least makes a little more sense clinically. Your preference would be for a nonequivalent group design because it gives patients a chance to have a hand in treatment decisions.

You are also not a big fan of third party insurance programs for similar reasons. Increasingly, they make treatment decisions regardless of what the patient or physician think is right (actually, they don't make the decisions -- they just tell you whether they are willing to pay!).

If the group seems to be heading towards a randomized experimental design, you might want to plan your strategy in advance. You could throw a tantrum and threaten to walk out of the meeting (although that wouldn't be very professional and you do believe it's important that a patients' rights person monitor the study throughout its life). You could express your strong displeasure and see if that helps. You could implicitly threaten. Something like "If you use that design I really can't predict how my association will react on behalf of patients' rights. They might launch a formal protest with their congressmen, with NIDA, or raise the issue in the public press." That ought to help!

In the end though, you have to recognize that you are just about the least powerful person on either team -- certainly you are on the Program Team. You aren't going to want to sever relationships with this project altogether -- you know you want an insider (you) monitoring things. Give it your best argument and then be prepared to live with whatever they decide.

Session #3: Consulting Coordinator (CC)

Confidential

At this next meeting, you are going to be presenting the major research design options. You should plan this presentation carefully and utilize all of the members of your team. You should also try to get your team to agree on the order of preference for these designs so you don't appear to be too disorganized going in to the meeting. Here's a suggestion for how you might proceed. Plan on presenting several designs. For each one, have the DC1 give both the notation and name and explain the mechanics. Have the DC2 talk about the major validity issues and trade-offs (especially the internal validity issues). Have the MC tell if there are any special measurement considerations and have the SC do the same for any statistical concerns. Then make a design recommendation and justify it. Finally, tell the program team that there is no one correct design for this or any other studay and remind them that any designb choice involves trade-offs and compromises. You can hedge at this point on your recommended design by telling them that although it's the Research Team's choice, the ultimate decision can only be made by the people who have to live with the implications and that's the Program team and especially the PD.

You should expect that you may be attacked on several grounds from different Program Team members. You should already be able to guess the major criticisms of some of them, like the MD or PA. Just remember that your role is entirely consultative and advisory. You're there to help them to make the choices, but they ultimately have to make them.

You may not have any problem in choosing a design. You and the Program Team might agree easily and quickly. If so, that's great. Just move on to other issues that are of concern. For instance, once a design is chosen, the work has only begun. You will have to begin to think through some of the implementation issues. For instance, how can you set up randomized assignment in a randomized experimental design or cutoff assignment in a regression-discontinuity design? What problems are likely to occur and how should the Program staff deal with them? What kind of monitoring will be needed to assure that things go well? What do you do if disaster strikes -- have you got a fall-back position? You probably won't have time to cover these at the next meeting, but you might, and you should begin to get ready for them anyway.

This will probably be a tricky meeting with potential for lots of conflict if you're not careful. If you just remember your role is consultative and advisory, you will probably be able to avoid the most serious potential problems.

Session #3: Design Consultant 1 (DC1)

Confidential

By now, you should be pretty familiar with the three basic research designs (randomized experiment, regression-discontinuity, nonequivalent group design). You should also begin thinking about different combinations of design features and what they might do for you. For instance, you should realize that you can couple or combine the regression-discontinuity and randomized experimental designs in a number of ways. Take a look at the article by Trochim and Land on Designing Designs for Research before the next meeting.

When you state a design formally, there are two major things you must do. First, you need to depict this design in design notation (using Xs and Os and whatever else is needed). For instance, you might use the following simple design:

R	O	X	O
R	O		O

or you might wind up with a more complex combination:

R		O	X	O		O
R		O		O		O
N	O	O	X	O		O
N	O	O		O		O
N		O		O	X	O

This last design has two groups which are randomly assigned and three nonequivalent groups. The timing indicates that there were several phases to the study. The first phase involved pretesting the first two nonequivalent groups. The second stage involved administering the treatment to one of the randomized groups and one of the nonequivalent groups. Also, in this second phase a last nonequivalent group was added and "double-pretested." The last phase involves a follow-up measure on the first four groups and administration of the treatment to the last nonequivalent group. You use an X to indicate a treatment, but if you are comparing multiple treatments (either with or without a control group) you could indicate this with subscripts (e.g., X_1 for inpatient and X_2 for outpatient). If you don't subscript observations (Os) it's assumed that the same test or tests are included each time. Subscripts are used with Os to indicate different tests or combinations of tests at different times. Usually, the formal statement of the design is followed by an explanation in text of each symbol. For instance, you might explain the first with:

where:

R means the groups are randomly assigned
O indicates a measure or set of measures
X indicates the treatment or program

Second, you need to state the exact name of the research design which was chosen. Examples are: a pretest-posttest two-group randomized experimental design, or a regression-discontinuity design with a cutoff interval with a two group nonequivalent group design within the interval. How do you put together a statement of the design name? Essentially you just assemble all the important parts or features that are in the design notation and string them together verbally. For instance, for the first design notated above, you might use the name: pretest-posttest treatment-control randomized experimental design. Obviously, the second design is much harder to describe in text. Here's how I might try it: "A pretest-double posttest treatment-control randomized experimental design coupled with a two-phase double pretest nonequivalent group design with a treatment-control in the first phase and treatment only group in the second." (Now you know why we use a notation system sometimes!) You don't have to be obsessive about it, just try to get the major features in. It doesn't really matter which order the words come in -- just try to get as much in as

possible and make it as readable as you can. If possible, it's nice if you can construct the notation exactly from the verbal description and vice versa.

At this next meeting, you are going to be presenting some of the major design options. Present several and for each one give both the notation and name. Be prepared to explain the mechanics of each one. And, you probably should also be clear about which you prefer and why. Also, don't let anybody (like the MD) intimidate you or push you around. The MD is likely to accuse you of being a sham scientifically if you suggest anything short of a randomized experiment. Just realize that anyone who takes a hard line on that position is living in a dream world. You don't recommend alternatives because you think they're preferable. You recommend them because you know (and any high-quality researcher) knows that you have to plan for the real world when developing a design. if you don't, you'll wind up with a study that falls apart later because people are unwilling to live with the restrictions the design places on them. Just remember, if the Program Team chooses a design that you don't recommend, they are the ones who will ultimately have to live with that choice. Your job is to give them your best advice (remember, you might be proven right in the end!).

Session #3: Design Consultant 2 (DC2)

Confidential

By now, you should be pretty familiar with different validity issues. You are probably going to be involved in presenting research design options to the Program Team. You should concentrate on the trade-offs in validity with different designs. For instance, you should definitely know what selection bias or selection threats are because they are central to the design choice issue. Read about selection threats to internal validity before the next meeting if you haven't already. Generally, you can point out how some of these trade-offs work. For instance, randomized experiments are generally considered the strongest designs against selection threats, but that's true only if they are correctly implemented! If people decide half way through the study that they can't live by the restrictions of that design, they might either overtly or covertly distort or cheat on the random assignment process. If that happens then you might be in worse shape than if you had just chosen some weaker design (with respect to selection threats) at the outset. There are also trade-offs in external validity or generalizeability. For instance, the regression-discontinuity design gives one treatment to the most severely ill and the other treatment (or a control) to those less ill. Can we generalize the results of the first treatment to the less severely ill patients? Doubtful. But we certainly could with a randomized experiment (if it doesn't fall apart!) because all treatments are given to patients from the full range of illness severity.

You should become a strong advocate for coupled designs and contingency plans or fallback strategies. For instance, to get the best of both worlds, you might recommend that they minimize selection bias by having some of the sample put into a randomized experiment, and still cover themselves ethically by having much of the sample assigned by a cutoff strategy. You and the DC1 are the two people everyone will count most on to give them these more creative ideas.

Session #3: Measurement Consultant (MC)

Confidential

You should be doing two major things. First, you should be reviewing some of the SCL90 materials in order to report at the next or some later meeting about that measure and its quality.

Second, and much more important, you should be thinking about the measurement implications of different design options. Here are some specific things you might look up and bring to your team. A randomized experiment doesn't technically require a pretest. Because of the random assignment, we assume that the groups are equivalent (at least probabilistically) so we don't need a pretest to examine this. Probably, this project will use pretests anyway because they need to do intake assessment. Perhaps more important is the idea of adding additional measures. For instance, we often add a double-pretest which turns a study into a "dry-run" experiment. Here is how we might notate this simple design in the randomized case:

R	O	O	X	O
R	O	O		O

The two waves of the pretest enable us to analyze them as though we had given the treatment. But if we find a treatment effect in the second pretest, we know something's wrong because we never even gave the treatment.

You should think about what each of the three major designs require in terms of measurement. Randomized experiments are probably the most straightforward, but will probably require some quality control check to assure that the patients are really being assigned randomly in the field. How could that be done? Regression-discontinuity designs require that people are assigned to treatment on the basis of some preprogram measure or measures. Does the Cocaine project have any measures which might make clinical sense for this task? Perhaps they will need to develop a simple rating measure of severity of cocaine abuse to accomplish this. Or, perhaps some already chosen measure like the SCL90 will be OK for this purpose. Nonequivalent group designs require lots of preprogram measurement because in the analysis you are probably going to want to try to adjust for the major variables on which groups might differ. For instance, if they decide to do a nonequivalent group design by just letting hospitals assign people as they normally would, you will want to measure the major ways in which people assigned to outpatient might differ from those assigned to inpatient. What should be included: ethnicity, religion, sex, SES, etc., etc?

Try to point out these different measurement implications for different design choices.

Session #3: Statistical Consultant (SC)

Confidential

Your job for the next meeting is to try to give people an idea of the implications of different designs for the statistical analysis. Your general pitch should be to keep the design simple (e.g., one of the "big three" -- randomized experiment, regression-discontinuity or nonequivalent group design) because they are all known and the statistical analysese have been worked out. The more people start creating variations on these designs, the more difficult the analyses will be, and the more they will rely on assumptions which might be questionable.

You should know how to describe in words the major type of analysis associated with the three major designs (even if you wouldn't have a clue at this point about how to do them). The randomized experiment is usually analyzed by and ANOVA (Analysis of Variance) model if there is no pretest and an ANCOVA (Analysis of Covariance) model if there is. The regresison-discontinuity design is analyzed using a polynomial regression form of an ANCOVA model, that is, it's like ANCOVA but also includes additional terms to try to take curvilinearity into account. Nonequivalent group designs are analyzed using reliability-corrected ANCOVA. If any of these three are chosen, the Trochim & Davis paper should be a big help in terms of giving an idea of how they are analyzed.

If it appears that the group is moving toward a more complex design variation even after you point out that it will complicate the analysis, don't worry. It may be very appropriate that they do so. You should probably take the position that whatever design they choose, they should probably do multiple analyses anyway (with different analyses based on different assumptions or differing reasonable models). See the relevant sections of the Reichardt chapter of the Trochim edited volume to get a flavor for this argument.

You might also want to look over the Rindskopf chapter in the Trochim edited volume. It describes analysis options when we have a potential for selection bias or selection threats. This is not a problem in well implemented randomized experiment or regression-discontinuity design, but is a problem if the assignment for either of those is not well implemented and in all nonequivalent group designs.

You may want to talk with others on you team to discuss what they know about statistics and what statistical programs they're familiar with. Also, find out what computers they know about. It's possible that you guys may be given some data to play around with! You might also want to play with some of the simulations in Trochim & Davis.

Session #4: Cocaine Treatment Study

Session #4: Project Director (PD)

Confidential

Five years have now passed! The Cocaine Study has been moving right along. Lots of problems and difficulties have arisen and been addressed. The data have already been collected. The statistical analysis is underway (although only for the key psychosocial valriable, the SCL90. Only preliminary cost data is available and, of course, you will need to allow a little more time to see what the relapse rates are like).

Two major things are going to happen in this 4th session. First, you are going to distribute the data from the project so that both teams can begin to work on the analysis. You will be responsible for making the data from the project available to the research team and to the other members of your program team. Second, you have received a memo from NIDA (enclosed) about the upcoming Site Visit review of your project. You and the GO are in charge of organizing this presentation, although it's expected that you'll have help from members of both teams.

Data Analysis. The data are already compiled and on two disks (one for a Mac and one for an IBM/PC) which you will get from the HA (the HA is the conduit for the data collection effort). Specific descriptions of the variables are included with the data. Your job is to try to make sure that a good, thorough, valid statistical analysis gets accomplished. There are two meajor features to the analysis, and it's your job to see that they both get addressed:

a) Descriptive Data Analyses. You want to have as thorough a description of the major features of the data as possible. This would include summary statistics for the whole group, for each treatment group, and for any treatment subgroups (e.g., any randomly assigned inpatients as differientated from RD assigned ones, if appropriate for your design). In addition, it is essential that you have a clear, accurate graph of the pre-post relationship which labels the treatments patients are in (a bivariate graph with the assignment measure on the x-axis, the SCL90 post measure on the y-axis, and an indication of which treatment each patient is in -- either by useing different graphing symbols or by showing cutoff values as vertical lines, or both if needed).

b) Outcome Analysis. You need to assess whether there are statistically significant treatment differences on the SCL90 measure. The analysis which you do depends on the specific design that you selected (here's where you may pay a price for getting fancy with the design!). The analysis will involve one or more regression models. For each regression model you will need to be prepared to summarize the results, including the overall F table and the individual regression coefficients, and especially concentrating on any key coefficients desctibing treatment differences.

As you may have guessed, this is not necessarily going to be easy or trivial! Nevertheless, as always you have lots of resources to draw upon. Probably the most important thing for you to realize is that you need to organize this effort. You have to use all of your management skills to find out what relevant expertise each of the project members has and to see that they all chip in on this task. You can expect that the statistical consultant has a pretty good idea of the analysis that needs to be done, but that doesn't necessarily mean the SC can just go off and do it. The SC may not know much of anything at all about computers or about specific statistical packages. You might want to do an informal polling at the project meeting to find out who on either team has what types of experiences.

The NIDA Site Review. The actual site review is in fact the final report for this project. The memo which you've received details what you need to do. You especially have two areas of responsibility. First, make sure that everyone on both teams is involved and has some responsibility. That doesn't mean that everyone should take part in the presentation -- things could be a bit crowded if you do that. But everyone should

pitch in and help on the upcoming site visit. Incidentally, it would not be appropriate for the GO to take part in the presentation itself. Second, you must make sure that time limitations are followed. NIDA doesn't need to know every nuance or wrinkle about your study. Address the issues they raise, but be concise and brief. You should probably rehearse the presentation. Handouts, overheads, and other aids may be helpful and can be used if you would like.

This is the last scripted session in the case study. Devote any other out-of-class project meetings to working on the data analysis and the NIDA site visit.

Session #4: Medical Director (MD)

Confidential

Five years have now passed! The Cocaine Study has been moving right along. Lots of problems and difficulties have arisen and been addressed. The data have already been collected. The statistical analysis is underway (although only for the key psychosocial valriable, the SCL90. Only preliminary cost data is available and, of course, you will need to allow a little more time to see what the relapse rates are like).

Two major things are going to happen in this 4th session. First, the data from the project will be distributed so that both teams can begin to work on the analysis. Second, the PD has received a memo from NIDA informing the project that there will be a Site Visit review. Your role in both of these activities is to help out in any way the PD thinks is sensible.

You also should be on the lookout for attempts on the part of the PA to undermine the credibility of the study. The PA will try to make the claim that the research design led to dropouts, treatment-related refusals, and other patient-related problems. As the friend of the PD, you will be in a good position to make a counter-argument more strongly than the PD can. You are also the most likely one to try to "stonewall it" on any patient-related problems -- just deny that they occured as frequently as the PA says, attack the PAs credibility and the credibility of the PAs sources, and all of the other bureucratic dodges that I'm sure you're familiar with. Don't overplay your hand, however. If you really get the PA ticked off, you run the risk that the PA will go independently to the Site Visit team -- and that could cause a lot of trouble.

Session #4: Grant Officer (GO)

Confidential

Five years have now passed! The Cocaine Study has been moving right along. Lots of problems and difficulties have arisen and been addressed. The data have already been collected. The statistical analysis is underway (although only for the key psychosocial valriable, the SCL90. Only preliminary cost data is available and, of course, you will need to allow a little more time to see what the relapse rates are like).

Two major things are going to happen in this 4th session. First, the data from the project will be distributed so that both teams can begin to work on the analysis. Second, the PD has received a memo (with a copy to you which is enclosed) from NIDA informing the project that there will be a Site Visit review. Your role in both of these activities is to help out in any way the PD thinks is sensible.

You especially have the responsibility to assist the PD in organizing the Site Visit presentation. Remember that you are the NIDA representative -- it's assumed that you have been through these reviews before on other projects for which you've had responsibility. Your main thrust should be to make sure that the presentation addresses the questions of the Site Review team. Don't let them wander into inconsequential issues. As for format, there is a lot of latitude, but make sure they do a professional job -- nothing too hokey!

Session #4: Hospital Administrator (HA)

Confidential

Five years have now passed! The Cocaine Study has been moving right along. Lots of problems and difficulties have arisen and been addressed. The data have already been collected. The statistical analysis is underway (although only for the key psychosocial valriable, the SCL90. Only preliminary cost data is available and, of course, you will need to allow a little more time to see what the relapse rates are like).

Two major things are going to happen in this 4th session. First, the data from the project will be distributed so that both teams can begin to work on the analysis. Second, the PD has received a memo from NIDA informing the project that there will be a Site Visit review. Your role in both of these activities is to help out in any way the PD thinks is sensible.

Your role in all of this is that you have been overseeing the collection of the data. Two disks are included with your script packet, one for a MAC and one for an IBM PC. They come with an explanatory memo which you should read carefully and then pass along.

You also should be on the lookout for attempts on the part of the PA to undermine the credibility of the study. The PA will try to make the claim that the research design led to dropouts, treatment-related refusals, and other patient-related problems. You have been closest to the data collection and treatment assignment efforts. Some of the PAs claims are undoubtedly true, but you can take the position that they don't seriously jeopardize the conclusions of the study. You might be the voice of compromise in any conflict. Suggest that an honest review of the project would include the concerns of the PA but that these need to be presented in their broader context -- problems with implementing the design did occur, as they always do in such studies, but they aren't that serious. Remember, the data tells you how many people dropped out after the study began. Can the data shed any light on whether patient-related implementation problems pose any serious threats? Just remember that if your team really gets the PA ticked off, you run the risk that the PA will go independently to the Site Visit team -- and that could cause a lot of trouble.

Session #4: Patient Advocate (PA)

Confidential

Five years have now passed! The Cocaine Study has been moving right along. Lots of problems and difficulties have arisen and been addressed. The data have already been collected. The statistical analysis is underway (although only for the key psychosocial valriable, the SCL90. Only preliminary cost data is available and, of course, you will need to allow a little more time to see what the relapse rates are like).

Two major things are going to happen in this 4th session. First, the data from the project will be distributed so that both teams can begin to work on the analysis. Second, the PD has received a memo from NIDA informing the project that there will be a Site Visit review. Your role in both of these activities is to help out in any way the PD thinks is sensible.

Your role in all of this should be to point out that the study was not necessarily as "clean" as some of the team members would like to make it seem. For instance, in your capacity as PA, you have been privy to rumors and confidences from patients who dropped out of the study. You should make up a few rumors and introduce them into the discussion. Some of my favorites are:

> "I talked with a patient who said that even though they scored below the criterion, the intake worker "snuck" them into the inpatient treatment."
>
> "I heard from several persons that they got assigned to a treatment that they didn't want and so they decided to drop out of the study."
>
> I heard rumors that a lot of potential patients who would have gone to the study hospitals decided to go to other hospitals when they found out about this study."

As always, you are a bit of a trouble-maker on this project. Try to do that without overplaying your hand. You have a real tightrope of a job to do. Your secret agenda is to find a way to communicate your concerns to the Site Review team -- if you're too strident, the PD might not allow you to take part in the presentation! Of course, you always have the option of going independently to the Site Visit team by writing a memo detailing your concerns. This is dangerous, however! You should only consider this if they try to cut you out entirely on the presentation of your concerns.

Session #4: Consulting Coordinator (CC)

Confidential

Five years have now passed! The Cocaine Study has been underway. Lots of problems and difficulties have arisen and been addressed. The data have already been collected. The statistical analysis is underway (although only for the key psychosocial valriable, the SCL90. Only preliminary cost data is available and, of course, you will need to allow a little more time to see what the relapse rates are like).

At the next project meeting, look to the PD to give you an idea of where the project needs to go from here.

One of the main issues is going to be the analysis of the data from the project. You should take a broad view on this. Recommend that there be multiple analyses, maybe even independent analyses by different sub-teams. For instance, you might have the SC and one DC do an analysis and the MC and the other DC do a separate analysis. Do they find similar results?

You should realize that the research team is not solely responsible for the entire analysis. Program team members can certainly be expected to help out on all phases, especially descriptive analyses. There may also be someone on the program team that has specific expertise in computing or statistics which you can draw on. Ultimately, this has to be a project effort.

You can count on the SC and MC to have a good idea of what statistical models need to be fitted to the data, but that won't guarantee that they can run the analysis. You have to be a good personnel manager to put together a complex analysis like this one -- get to know the strengths and weaknesses of your team members.

Session #4: Design Consultant 1 (DC1)

Confidential

Five years have now passed! The Cocaine Study has been underway. Lots of problems and difficulties have arisen and been addressed. The data have already been collected. The statistical analysis is underway (although only for the key psychosocial valriable, the SCL90. Only preliminary cost data is available and, of course, you will need to allow a little more time to see what the relapse rates are like).

One of your big roles in the remainder of the project is to defend the design choice against unreasonable criticisms. One major thing to check is how well the cutoff assignment rule was followed. Are there any cases of persons being placed in the wrong treatment given their assignment measure score? Also, take a good look at the patterns in the results. Your design is strong because it creates a specific unusual pattern in the data which is not likely to occur by itself, or in natural circumstances. Plots of the data may be very convincing.

Remember also that we always expect that there will be some error in implementing a design. For instance, it's virtually inevitable that there will be some dropouts. But, if the proportion of these to the entire sample is relatively small, it's not likely that they will bias the results seriously.

Finally, remember that this is a relative comparison study -- there is no true no-treatment control group. Thus, all conclusions must be stated relatively. You cannot claim that either treatment works in an absolute sense -- both treatments could actually be worse than no treatment at all (e.g., spontaneous remission) and there's no way to really know if that is the case in this study. Nevertheless, you can argue that such a result would be unlikely and implausible and that the explicit purpose of this study was to examine the relative effectiveness anyway. From a policy or treatment point of view, a no-treatment option is just not palatable -- doctors are going to give some kind of treatment and this study attempts to shed some light on the relative advantages of the two most common treatment types.

Session #4: Design Consultant 2 (DC2)

Confidential

Five years have now passed! The Cocaine Study has been underway. Lots of problems and difficulties have arisen and been addressed. The data have already been collected. The statistical analysis is underway (although only for the key psychosocial valriable, the SCL90. Only preliminary cost data is available and, of course, you will need to allow a little more time to see what the relapse rates are like).

One of your big roles in this study is to defend the overall validity of conclusions. You need to recognize right off the bat that this study does not prioritize on external validity. In an extreme sense, this study couldn't care less whether the results are readily generalizeable. It's likely that they are, to some extent, but this study was not constucted to assure a high level of external validity.

Instead, the purpose of this study was to find out whether there is a relative difference in the effectiveness of the two treatments in this context. If the results clearly point to an effect, NIDA can then implement other studies to see if the effect holds in other places or times.

Thus, when people raise questions about whether the cocaine users in the study are representative of even the cocaine users in the metropolitan area, you should concede that they are not, and that assuring representativeness was not a priority in this study.

There will be many other validity issues which may come up. Be sure you re-read relevant stuff on validity to prepare to adress these.

Session #4: Measurement Consultant (MC)

Confidential

Five years have now passed! The Cocaine Study has been underway. Lots of problems and difficulties have arisen and been addressed. The data have already been collected. The statistical analysis is underway (although only for the key psychosocial valriable, the SCL90. Only preliminary cost data is available and, of course, you will need to allow a little more time to see what the relapse rates are like).

Becuase you are the MC, you are expected to have some knowledge of statistics. So that you can help the SC (who is liable to feel pretty lonely in this effort) I am enclosing the same information that goes into the SCs script regarding specific statistical analysis. Work with the SC. Help each other try to understand this. Here is what the SC got:

At the next project meeting the research team is going to be given the data from the project. You will be expected to guide the key statistical analysis assessing the relative effectiveness of the treatments. To help you, the major analytic model for your analysis is presented below. This model is, however, only a general structure for the analysis. You should probably encourage the project to conduct a number of different analyses to see if they yield different results or if they converge on a single estimate. For instance, if you coupled a randomized experiment with an RD design, you should probably do one analysis of the randomized data, a separate one of the RD-only data, and one with all data combined. Also, just because you're the SC doesn't mean that you are expected to know how to run the analysis. A statistician may be largely a theoretician -- you are expected to know the theoretical model (given below) but may not know how to use a computer or a specific computer analysis package. Point that out to other team members if you need to. Both teams need to find out who knows how to use a computer and who has had experience with data analysis.

Anyway, here's a formal statement of the general regression model for your analysis. Remember, you may want to do several different sub-analyses depending on your specific design. The model can be stated as:

Given a pretest assignment measure, x_i, and a postprogram measure, y_i, the model can be stated as follows:

$$y_i = \beta_o + \beta_1 x_i^{\sim} + \beta_2 z_i + e_i$$

Where:

- $x_i^{\sim}$ = preprogram measure for individual i minus the value of the cutoff, x_o (i.e., $x_i^{\sim} = x_i - x_c$)
- y_i = postprogram measure for individual i
- z_i = assignment variable (l if program participant; 0 if comparison participant)
- s = the degree of the polynomial for the associated $x_i^{\sim}$
- β_o = parameter for comparison group intercept at cutoff
- β_1 = linear slope parameter
- β_2 = program effect estimate

The major hypothesis of interest is:

$$H_0: \beta_2 = 0$$

tested against the alternative:

$$H_1: \beta_2 \_ 0$$

What does all of this mean? First of all, you will be given the x_i, y_i, and z_i data for each participant. If you tell the regression analysis program that you want to regress the posttest scores (y_i) onto the other two(x_i, z_i), you will get the three β values as output from the program. The key output is the value which tells you the relative treatment effect -- β_2. this is a positive number, then the SCL90 scores increased for the inpatient group over what is expected relative to the outpatients. A negative value would be evidence that inpatient treatment lowered the SCL90 scores relative to outpatient -- that inpatient was more effective (remember that lower scores mean better psychosocial functioning).

One of the trickiest decisions in these analyses concerns where to estimate the treatment effect. In a traditional single cutoff RD, you estimate the effect at the cutoff, but when you use cutoff intervals or multiple cutoffs, this gets trickier. Why does this make a difference? Because you must subtract the value from all pretest scores before running the analysis (as indicated in the above model). I would recommend trying multiple analyses with a few different cutoff points to see if it makes much of a difference. If you have a cutoff interval, you might subtract the midpoint of that interval, for instance. The important thing to remember is that within each individual analysis, you subtract only one value from all pretest scores (inpatient and outpatient) and that value is specifically where the treatment effect will be estimated.

So, here are the steps in each analysis. First, decide on whether the specific analysis will be for the the entire dataset or only a subset. Second, if RD data are involved, decide on where the treatment effect will be estimated (i.e., choose a cutoff value). Third, have your analysis program subtract this value from each pretest score. Fourth, run the general regression model given above. Fifth, examine the treatment effect estimate (the coefficient β_2 associated with z_i) to see which direction it's in and whether it is statistically significant.

In addition to these analyses there will also be descriptive statistics to run and graphs to produce. Look carefully at the graphs to see that the statistics make sense given the visible data patterns. Good luck.

Session #4: Statistical Consultant (SC)

Confidential

Five years have now passed! The Cocaine Study has been underway. Lots of problems and difficulties have arisen and been addressed. The data have already been collected. The statistical analysis is underway (although only for the key psychosocial valriable, the SCL90. Only preliminary cost data is available and, of course, you will need to allow a little more time to see what the relapse rates are like).

At the next project meeting the research team is going to be given the data from the project. You will be expected to guide the key statistical analysis assessing the relative effectiveness of the treatments. To help you, the major analytic model for your analysis is presented below. This model is, however, only a general structure for the analysis. You should probably encourage the project to conduct a number of different analyses to see if they yield different results or if they converge on a single estimate. For instance, if you coupled a randomized experiment with an RD design, you should probably do one analysis of the randomized data, a separate one of the RD-only data, and one with all data combined. Also, just because you're the SC doesn't mean that you are expected to know how to run the analysis. A statistician may be largely a theoretician -- you are expected to know the theoretical model (given below) but may not know how to use a computer or a specific computer analysis package. Point that out to other team members if you need to. Both teams need to find out who knows how to use a computer and who has had experience with data analysis.

Anyway, here's a formal statement of the general regression model for your analysis. Remember, you may want to do several different sub-analyses depending on your specific design. The model can be stated as:

Given a pretest assignment measure, x_i, and a postprogram measure, y_i, the model can be stated as follows:

$$y_i = \beta_o + \beta_1 x_i{}^{\sim} + \beta_2 z_i + e_i$$

Where:

- $x_i{}^{\sim}$ = preprogram measure for individual i minus the value of the cutoff, x_o (i.e., $x_i{}^{\sim} = x_i - x_c$)
- y_i = postprogram measure for individual i
- z_i = assignment variable (l if program participant; 0 if comparison participant)
- s = the degree of the polynomial for the associated $x_i{}^{\sim}$
- β_o = parameter for comparison group intercept at cutoff
- β_1 = linear slope parameter
- β_2 = program effect estimate

The major hypothesis of interest is:

$$H_0: \beta_2 = 0$$

tested against the alternative:

$$H_1: \beta_2 \_ 0$$

What does all of this mean? First of all, you will be given the x_i, y_i, and z_i data for each participant. If you tell the regression analysis program that you want to regress the posttest scores (y_i) onto the other two(x_i,

z_i), you will get the three β values as output from the program. The key output is the value which tells you the relative treatment effect -- β_2. this is a positive number, then the SCL90 scores increased for the inpatient group over what is expected relative to the outpatients. A negative value would be evidence that inpatient treatment lowered the SCL90 scores relative to outpatient -- that inpatient was more effective (remember that lower scores mean better psychosocial functioning).

One of the trickiest decisions in these analyses concerns where to estimate the treatment effect. In a traditional single cutoff RD, you estimate the effect at the cutoff, but when you use cutoff intervals or multiple cutoffs, this gets trickier. Why does this make a difference? Because you must subtract the value from all pretest scores before running the analysis (as indicated in the above model). I would recommend trying multiple analyses with a few different cutoff points to see if it makes much of a difference. If you have a cutoff interval, you might subtract the midpoint of that interval, for instance. The important thing to remember is that within each individual analysis, you subtract only one value from all pretest scores (inpatient and outpatient) and that value is specifically where the treatment effect will be estimated.

So, here are the steps in each analysis. First, decide on whether the specific analysis will be for the the entire dataset or only a subset. Second, if RD data are involved, decide on where the treatment effect will be estimated (i.e., choose a cutoff value). Third, have your analysis program subtract this value from each pretest score. Fourth, run the general regression model given above. Fifth, examine the treatment effect estimate (the coefficient β_2 associated with z_i) to see which direction it's in and whether it is statistically significant.

In addition to these analyses there will also be descriptive statistics to run and graphs to produce. Look carefully at the graphs to see that the statistics make sense given the visible data patterns. The MC will also be given this information about the correct model for analysis because both of you are expected to have some statistical knowledge. Work together and help each other out. Good luck.

Appendix A: Cocaine Study Fact Sheet

Question	Answer	How Answered
SESSION 1		
How many hospitals in NortheastNet?	NortheastNet has 10 hospitals	HA 1-Script
SESSION 2		
What is the basis/motivation for this research?	Federal Government initiative	GO 2-Script
Can we obtain more info re hospitals, and demographics re patients? How many people does each clininc serve? What is the estimated size of the drug using population each clinic serves?	All of the information we currently have is supplied.	MD 2-Script HA 2-Script MD 2-Tables 1-3, Document HA, 2-Standards for diagnosis and treatment, Document
Are there any past evaluations of existing programs? Are there any studies of different causes of drug use in different subgroups (e.g., male/female, blue collar/professional)? Any literature on cocaine abuse programs and their effectiveness? Any literature on cocaine abuse programs and their effectiveness?	All of the prior research that we have is documented in the excerpts from the research proposal. In addition, the recent literature on alcohol treatment effectiveness includes a meta-evaluation of about twenty different studies comparing inpatient versus outpatient treatment of alcohol abuse. The bottom line was that it was clear that there was no significant effectiveness between the two treatments. Consequently, because inpatient treatment is so much more expensive, outpatient treatment is significantly better in terms of cost effectiveness and cost benefit figures. If I can find my copy of this article, I'll get it to you, but you probably don't need it.	PD 2-Script PD 2- Background and Significance from original proposal, Document
Do any hospitals object to being involved?	"the others were not necessarily against the study but did not wish to participate because they didn't offer one or both treatments, or they didn't want to spare the resources which participation might involve"	HA 2-Script
What is our budget? What cost boundaries are required for the research team to be aware of?	On the issue of budget, you should not disclose to the research team how big the project budget is. You should simply inform them that you believe that you have more than sufficient funding to do a high-quality job and that their (the research team's) role is to advise you on the best methodology to us to answer the research questions. You don't have to be nasty about this -- just keep the research team focused on their job and tell them that funding is your responsibility.	PD 2-Script
Is it possible to get more info re sample size and makeup, etc.?		PD 2-Excerpt from proposal, document MD 2-Tables 1-3, Document

We need a list of in/outpatient facilities and descriptions of each, such as size and population served. How many inpatient and outpatient programs are there? What are the demographics of each hospital participating? - size (max number of patients) - location - public or private - characteristics of patients (ethnicity/occupation) - admittance procedures - are programs standardized or same across hospitals?	All the data we have: ***Site 1*** Capacity: 40 inpatient(IP) slots; 30 outpatient(OP) On average, 41 IP, 17 OP admits per month approx. 23 cocaine admits/month (40% of all patients) ***Site 2*** Capacity: 28 inpatient(IP) slots; 72 outpatient(OP) On average, 24 IP, 14 OP admits per month approx. 13 cocaine admits/month (32% of all patients) ***Site 3*** Capacity: 36 inpatient(IP) slots; 50 outpatient(OP) On average, 35 IP, 3 OP admits per month approx. 7 cocaine admits/month (21% of all patients) ***Site 4*** Capacity: 39 inpatient(IP) slots; 25 outpatient(OP) (No average monthly admissions data available) approx. 5-15 cocaine admits/month	HA 2-Script MD 2-Tables 1-3, Documents HA, 2-Standards for diagnosis and treatment, Document
Will the same patients be involved over the life of the study?	The study will utilize all patients at the four participating hospitals who meet treatment criteria at any time during the study's duration.	PD 2-Script
What is the male/female patient ratio? professional/blue collar? What proportion of the estimated drug population in each demographic group is seeking treatment?	All the info we have is presented	MD 2-Tables 1-3, Document
What are the major research hypotheses we're trying to test? What are the actual objectives of the study. To find out whether to channel more serious addicts to inpatient, to evaluate relative cost-benefits, or to determine relative benefits?	Main Hypothesis: Inpatient treatment for persons with more severe cocaine dependence and psychosocial impairment results in better outcomes than outpatient treatment. also, see proposal excerpt	PD 2-Script PD 2-Excerpt from proposal, Document
What are the rates of relapse back into the programs?		PD 2-Excerpt from proposal, Document

How do people come to treatment?		PD 2-Excerpt from proposal, Document
Which area is each program located?	Geographically, ther is one site from each of the four major sectors/quadrants of the city.	HA 2-Script
What drug education programs and drug related social work programs are in the area? What is the amount of drug-related treatments in other sectors - e.g., profit-making clinics.	We really do not have any data on the numbers and types of alternative treatment programs which are available. In fact, many of these are informal, poorly documented or parts of other kinds of programs which fall under the jurisdiction of differing Federal, State and Local agencies. It would be very difficult to get comprehensive information on available treatment alternatives.	HA 2-Script
How much funding does each clinic receive?	We have no specific information about the funding of each site's treatment units at this time. Obviously, we will have to negotiate with each site to make available the necessary financial data for any cost-related hypotheses.	HA 2-Script
What are the staffing levels of each clinic?	We also have no specific data on the staffing levels of all four sites, although we expect that per patient rates are comparable because they all follow the same treatment protocols.	HA 2-Script
What are the neighborhood characteristics of the program users (urban, suburban, poor)? Employment characteristics in neighborhood of clinic?	In general, the patient populations are similar in characteristics to populations of most cities in typical U.S. northeastern cities (e.g., Buffalo, Syracuse, Worcester, are examples).	HA 2-Script
What are the differences in the degree of chemical dependency of inpatient / outpatient?	see the Standards document (from HA) and the Definitions of Disorders/Diagnostic Criteria Document (from MD)	MD 2 -Definitions of Disorders/Diagnostic Criteria Document HA 2-Standards document
What research design should be used and what are the options for a randomized design?	We do not have any research design currently chosen. We expect that a randomized experiment would be the strongest method available to answer the research questions, but we have some concerns about the ethics of randomly assigning persons to treatments and about the degree to which hospital staff would be willing to implement this. For instance, we are concerned that even if we assign a person at random to receive outpatient treatment, if the hospital staff feels that person is sick enough to warrant more intensive inpatient treatment, they may find ways to move the person to that condition. This would jeopardize our results. We are essentially asking the research team to advise us on either how to control these kinds of problems or on design alternatives which still meet standards of rigor.	PD 2-Script

Why is the sample population simply workforce?	The sample is limited to only those who are in the work force because they make up the vast proportion of clients at NortheastNet Hospitals and because they are in a position to pay for service, or have insurance to cover it. If significant effects are found in this study, it is likely that it will be desirable to replicate it on other, non-working samples.	PD 2-Script
Budget of grant? How distributed?	Not research team's business	PD 2-Script
How have drug treatment outcomes been measured in prior studies?	Details about the measures we will use are provided in the excerpts from the proposal. These are all standard measurement constructs for this type of research and have been used in other studies. We have had prior research experience with all of the measures except for the Symptoms Checklist 90 (SCL90). We would especially like the research team to concentrate on that measure and address the following: 1. What is the reliability of this measure? 2. What is the validity of this measure? I'm giving you a copy of the documentation which came with the measure. It includes a copy of the complete measure and accompanying information. Please report back to us next time on what you find out about the measure.	PD 2-Script PD 2-excerpts from proposal PD 2-SCL90 materials
Is the decision-making process integral to the treatment, that is, if we take this out of the hands of the physician and patient, are we changing the treatment?	No, all hospitals currently admit through intake procedures which are separate from the treatment.	
Will we get a copy of the proposal submitted to funding agency?	excerpts	PD 2-excerpts from proposal
What are the definitions of "effectiveness" "psychosocial functioning" "drug use"		PD 2-excerpts from proposal
Will research team have access to patient data? If so, what data?	Some data may be made available to you at a later date. We have program staff who will do all preliminary and descriptive data analysis. What we will need your help on is the data to analyze the outcomes to assess the major research questions. We are likely to give you the relevant outcome data as soon as we have enough to make some preliminary analyses reasonable.	PD 2-Script
How many patients are addicted to other drugs? Which drugs?		PD 2-excerpts from proposal
What specific treatment methods will be used in inpatient and outpatient (e.g., drug therapy, counseling)?		PD 2-excerpt from proposal HA 2-Standards document

Is there a contact person in each hospital? Who?	You should know that we are in the process of hiring staff for this project. We will have a program staff member on each site, in addition to central staff responsible for data management, preliminary data analysis, project implementation, and so on. For now, all direct contacts with the four participating sites are through the HA.	PD 2-Script
What are NIDA's internal guidelines for the study?	A second question -- and one that is likely to recur throughout this study -- concerns what NIDAs guidelines are. You can tell them that due to the large number and variety of studies which NIDA sponsors, there are no written, off-the-shelf guidelines. You should stress that the reason you are there in person is to be able to insure that whatever is done meets acceptable standards for high-quality research. What is "high-quality" research? Refer them to Cook & Campbell, Judd & Kenny, and the Trochim volume as three sources for determining what high quality research is!	GO 2-Script
What is meant by cocaine dependence?	See document.	Definitions of Disorders/Diagnostic Criteria (class materials)

Appendix B: Site Visit Protocol

NIDA

The National Institute on Drug Abuse

Federal Beltway Building
Washington DC 11111

To: Program Director, Grants Officer
From: Project Review Site Visit Coordinator
Re: Site Visit to Review Cocaine Study
Date: Near the end of your five year project, 1995

As your project approaches completion, it is customary procedure for NIDA to send an independent Site Review team to visit the project and discuss specific research-related questions and concerns. Your site visit is scheduled for the week of March 26th-30th. We will give you specific dates as the time approaches. You may recall from our prior conference call that the format for this is fairly simple. You are to prepare a short summary of the project (no more than 20 minutes). In this presentation you must describe the research design, present the major results (at least for the key psychosocial variable which I understand you have already begun analyzing), and explain how valid you think this study is. In addition, you must briefly address each of the major written questions (see attached), also within that 20 minute presentation. The format for the presentation, choice of speakers, and so on, except for these constraints, is entirely up to you. There will then be a period of 15 minutes during which the site visit team members will be able to ask any additional questions which might arise.

I know that a site visit is seldom seen as a positive experience -- it requires that you put aside other things and attend to the preparations. Nevertheless, it has been our experience at NIDA that these project review site visits are an important part of the preparation to make the results of your study public. Our goal is to help you to anticipate any potential major criticisms now, rather than be surprised by them later.

Thank you for your time. I look forward to hearing the specifics about your outstanding project.

Site Visit Advance Questions

The site visit team has put together a series of questions concerning issues related to your project about which they are unclear or for which they wish more detailed explanation. In addressing these questions in your presentation, be as brief and concise as you can.

1. **Program-related questions**. Over the course of your study, there was a strong trend nationally away from either inpatient or outpatient treatment for cocaine abuse and toward day-treatment (here, day treatment is considered any program which requires full-time, five-days-a-week all day in hospital treatment and allows the patients to go home in evenings and on weekends). Many of the hospitals in NortheastNet have also moved to this option because it is thought to be less expensive than inpatient treatment and more effective than outpatient. How did you deal with the pressures to implement such an option at study hospitals? Did any of the study hospitals implement such programs? How did you deal with third party insurers who might be expected to prefer this option to inpatient care? How does this issue affect the validity of your study?

2. **Treatment Assignment Issues**. Your study used assignment by cutoff on a preprogram measure. You stated in an project memo early in the study that this design required strict adherance to the cutoff rule. How confident are you that this was accomplished correctly? How did you monitor or control assignment? It is likely that the intake persons in each hospital would want and need to know the specific cutoff values. But, if they know the cutoff values, wouldn't they be able to find ways to "fudge" the assignment to insure that persons they think need a treatment get it? Did you tell them what the cutoff(s) was? If yes, how can you be sure they weren't "sneaking" patients into treatments either by altering the test results or simply misassigning? if you didn't tell them the cutoff(s), how did you deal with the resentment we would expect from professionals who believe it is their ethical, legal and professional responsibility to assign patients appropriately to treatments?

3. **Treatment-Related Refusals**. In any study of this type we know there are likely to be patients who for various reasons will refuse to be assigned to certain treatments. For instance, some patients might not want to go into a hospital inpatient treatment because it would take them away from family or jobs for a period of time. Or, patients may not be willing to go into outpatient treatment if they feel it will be ineffective or that it is really just a low-cost option. How did you deal with this problem? How did these issues affect the validity of your study?

4. **Dropouts**. In even the best-controlled studies, there is inevitably some percentage of post-assignment treatment drop-outs. What were the dropout rates in this study? What steps did you take to reduce dropouts? Were dropout rates equivalent for the two treatment groups? Since you used a cutoff-based assignment, isn't it likely that your dropouts in each treatment were different types of people and dropped out for vastly different reasons? For instance, isn't it likely that there would be greater dropouts during treatment in the outpatient group because your inpatients are a captive audience? How did you deal with dropout-related problems? How do they affect the validity of your study?

5. **Analysis Model**. In the traditional RD design, we use a no-treatment control group to show us what the pre-post relationship is in the absence of the treatment. But in this study, there is no no-treatment conrol. Rather, there are two treatment groups. If both treatments have an effect, isn't that likely to change the regression lines in both groups (either their slopes, their shapes, or both)? Doesn't that likelihood invalidate your standard of comparison in this RD design? How is it possible to even take that into account in this study? How do you answer the criticism that this is a fatal flaw in the study -- that you should have included a no-treatment control group?

Data Memo

NortheastNet

A Consortium of Metro Area Hospitals

1234 Medical Concourse
Metro, ST 11111

To: Hospital Administrator, Cocaine Project PD
From: Data Management Director, NortheastNet
Re: Cocaine Project Data
Date: March 30th, 2015

Attached is a file that has the complete dataset for all of the Cocaine Study data collected to date

Each dataset has 500 cases. Each case is one row on the dataset. Variables are delimited by the tab character.

Each row of the dataset therefore looks like:

Assignment Measure <delimiter> Treatment <delimiter> Posttest <delimiter> Method of Assignment <delimiter> Average Cost Per Day <Return>

For instance, a line of data might look like:

51.378, 0, 182, 2, 124.58

If this is the case, this can be interpreted as the following:

51.378	is the value of the assignment measure. It is assumed that the assignment measure is a composite variable that has a possible range of 1 to 100 and that the cutoff values for the random assignment interval were 40 and 60 (all cases less than and equal to 40 are assigned to outpatient; all cases greater than 60 to inpatient with exceptions as noted below; all cases between these were subject to random assignment)
0	is the treatment condition for this case, where 0=Outpatient and 1=Inpatient
182	is the posttest SCL90 value
2	is the method of assignment where: 1is RD assignment; 2 is RE assignment; and 3 is a person who refused to accept the assignment procedure and self-selected their treatment (nonequivalent assignment)
124.58	is the average dollar cost per day for the treatment

For all variables, a 'period' is used if the variable is missing for that case.

The rest of the data for the project is currently being assembled and I should get it to you soon. This includes the other post measures and relapse rates. The data enclosed here should give you something to begin analyzing anyway.

Please don't hesitate to let me know if there is a problem in the data. I'm confident that the dataset is as accurate as it can be. Thank you.

Student Grading Sheet

Instructions: Write the name of each of the other students in your project on the lines provided. Next to each name circle a score for overall effort and a score for overall quality of performance for the project. We all know that ratings of this type are subjective and that they are subject to bias. Just be as fair as you can be and do as good a job as possible based on your contact with the student. Use the scale provided to decide which numbers to give. Your ratings will be kept totally confidential and will never be shown to other students (only averages will). Don't forget to rate yourself in the appropriate spot.

Your Name _____ Project Name _____

Please check your team and which role(s) you played:

Team (check one):	☐ Program	☐ Research
Role(s):	☐ Program Director (PD) ☐ Medical Director (MD) ☐ Health Administrator (HA) ☐ Grant Officer (GO) ☐ Patient Advocate (PA)	☐ Consulting Coordinator (CC) ☐ Design Consultant 1 (DC1) ☐ Design Consultant 2 (DC2) ☐ Measurement Consultant (MC) ☐ Statistical Consultant (SC)

Scale for the ratings:

1	2	3	4	5	6	7
Extremely Below Average	**Moderately Below Average**	**Somewhat Below Average**	**About Average**	**Somewhat Above Average**	**Moderately Above Average**	**Extremely Above Average**

Some suggestions. Extremely poor refers to the lowest level of performance. If someone seldom showed up or almost never contributed then you might use this rating. If they contributed a little, use a 2 or 3. If their contribution was about what we should expect of a Cornell graduate student on this type of assignment, use a 4. Use 5 or 6 if their performance exceeded what we would expect from a Cornell graduate student on this assignment. Reserve a 7 rating for those who clearly contributed the most (you should not have too many sevens!).

Student Name	Overall *Effort*	Overall *Quality*
PROGRAM TEAM:		
Program Director (PD):	1 2 3 4 5 6 7	1 2 3 4 5 6 7
Medical Director (MD):	1 2 3 4 5 6 7	1 2 3 4 5 6 7
Health Administrator (HA):	1 2 3 4 5 6 7	1 2 3 4 5 6 7
Grant Officer (GO):	1 2 3 4 5 6 7	1 2 3 4 5 6 7
Patient Advocate (PA):	1 2 3 4 5 6 7	1 2 3 4 5 6 7
RESEARCH TEAM:		

Consulting Coordinator (CC)	1 2 3 4 5 6 7	1 2 3 4 5 6 7
Design Consultant 1 (DC1):	1 2 3 4 5 6 7	1 2 3 4 5 6 7
Design Consultant 2 (DC2):	1 2 3 4 5 6 7	1 2 3 4 5 6 7
Measurement Consultant (MC):	1 2 3 4 5 6 7	1 2 3 4 5 6 7
Statistical Consultant (SC):	1 2 3 4 5 6 7	1 2 3 4 5 6 7

Please enter any comments about the work you observed that you feel was not captured well by the ratings (all information is absolutely confidential):