When you Consult a Statistician . . .
What to Expect

Section on Statistical Consulting
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When you consult a statistician, you enlist the help of a professional who is particularly skilled at solving research problems. The statistician will try to guide you to the best way to obtain an answer to your research questions.

The aim of this brochure is to provide you, as a potential client or employer of a statistical consultant, with an overview of what is involved in a consultation. The sections address such topics as when it is useful to consult a statistician, the responsibilities of statistician and client, and what to expect as you initiate and continue a working relationship with a statistician, including a brief summary of the ethical principles that guide statistical work

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I. What is Statistical Consultation?

In a statistical consultation, you seek the help of a statistician to select and use the best methods for obtaining and analyzing data for some data-related objective. Usually the objective is to answer a question. The subject area could be almost anything, such as business management, government, agriculture, economics, or a science.

A. Do you need a statistical consultant?

A statistical consultant has technical expertise and experience in areas such as planning studies, measurement and sampling methods, data quality management, and statistical analysis and interpretation. A statistical consultant is a problem solver. The statistician's specialized knowledge can supplement your own expertise to enhance the integrity and validity of your study.

A statistician is especially helpful when

- You know what you would like to find out and want help to design a study that will answer your questions. You want help determining how large a study to perform or how many different groups to compare.

- A study involves methods and/or responses that may be different from those to which you are accustomed. Different types of data are analyzed in different ways, and a statistician can determine appropriate methods of analysis for each type.

- A planned study takes an unexpected twist. Rather than improvise and hope for the best, consult a statistician who can help to weigh the merits and drawbacks of different possible actions.

- The size of the study results in a volume of data that is more than you are prepared to handle yourself. A statistician can navigate through large data sets to arrive at specific answers to your questions.

- The analytic method appropriate for your data is complex or difficult to use successfully and requires more applied experience than you have.

- You have done similar projects but would like to get a new point of view and/or take advantage of the latest methods of design and analysis.

- You simply prefer to rely on a professional statistician for advice and support on all methodological aspects of your project.

A statistician can also help to interpret the results of an analysis that you have or another person has performed and can evaluate whether a study design or an analysis is appropriate for addressing the problem at hand.

B. Roles of a Statistical Consultant

The role a statistician plays in a research study depends on the study's resources and

needs. A statistician can be a full **collaborator** or **partner** in research, especially if the statistician is familiar with the problem being studied. Regular meetings or discussions cover many aspects of the study, and each collaborator educates the other throughout the course of the collaboration.

The particular activities and deliverables for which the statistician collaborator takes responsibility are negotiated in each project. These may involve the statistician in any or all project activities from planning through final report or publication.

Alternatively, the statistician may remain somewhat more distant from ongoing project activity, acting more as a technical **advisor** who is available to answer questions that might arise.

This is an appropriate level of involvement when, for example, a researcher feels comfortable with his ability to design the study and/or carry out the data analysis and needs help only with specific choices. A statistical advisor may be consulted at every stage of the study, from design to reporting, or may be needed only at one time.

You may view the assembled personnel who work on your project as a team. One context where this occurs is when the statistician is an employee in your organization. In this situation, the statistician is a **team member**, to whom you may delegate the aspects of the project that appear to fall within her area of expertise.

Regardless of the particular role you assign to a statistician, she will take on certain responsibilities as a matter of course. She will evaluate the project and any requests you make from the viewpoint of a technical expert, and may see issues or problems that are not obvious to you. So even in the role of team member, a statistician is likely to offer advice on procedures and interpretation of results. She also has a code of professional ethics (see Section V), which can affect how she responds to a situation.

C. How to Involve a Statistical Consultant

Prior to Data Collection. The most effective way to work with a statistical consultant is to include her from the very beginning of the project. A statistician who is also knowledgeable in your area of research can be of great value in helping to refine and focus the research effort into an efficient, successful project.

An important advantage of consulting a statistician before a study begins is that she can verify that the planned procedures and size of the study will be adequate to address its goals. She can give advice on blinding/masking and randomization, the number and combination of experimental interventions, the timing of measurements or visits, and other important design issues, such as whether it would be better to collect information on a larger sample or on the same sample more times.

A statistician can also suggest ways to maximize the efficient use of the available resources. It may seem that using a particular design is sensible, but in fact, the statistician may know a more efficient design. Also, a statistician routinely looks for threats to validity that might ruin a project.

The statistician can also contribute relevant expertise in decisions about data management from the earliest stages. Decisions about how to code measures, and what to computerize, directly affect the ease, even the feasibility, of subsequent analyses.

If the statistician is consulted before the data management system is established, the items below should be discussed. If the database already exists, the statistician will need to know how all of these aspects of data management were carried out, often in detail.

- Who will be responsible for data management?

- Confidentiality of subject information.
- Data integrity and security.
- Coding guidelines and documentation.
- Computer software and hardware.

Judicious use of a statistical consultant in the early stages of a project can save much time, effort, and aggravation in the later stages. "It is always easier to steer a ship than to raise it off the ocean floor."

After Data Have Been Collected. Although it is best to involve a statistician in the design of a study, a statistical consultant may be brought into a project after the data have been collected.

A statistical consultant can help to select and implement data analysis methods that are appropriate and effective for the types of data produced by your study. In order to do this, the statistician needs to have a complete, detailed description of the study design and conduct, as well as a clear exposition of the questions to be addressed.

A statistician should know (or may be able to develop) statistically valid ways to obtain answers to your questions. Also, she will examine your data for threats to validity, ranging from missing data to questionable outliers to confounders.

If the study procedures did not provide data that could answer the research question, the statistician will not be able to remedy this with statistical methods; however, she may be able to point out what information *can* be extracted from the data.

Once the data are analyzed, the results must be interpreted and conveyed to an audience, such as a regulatory agency, management, a research journal, or a media outlet. A statistician can be valuable at this stage, too, by checking that your conclusions fit the analysis results, by suggesting the best ways to describe and display the data, and by assuring that you have not made erroneous or incomplete statements about the findings. A statistician who is first consulted at this stage may want to re-analyze the data using methods she considers more appropriate than those already tried.

D. What To Look For in a Statistical Consultant

If you can choose your statistical consultant, you should select one who:

- Has a good general knowledge of statistics, and keeps up-to-date with the current literature;
- Is a good problem solver with a sincere desire to solve real problems;
- Has excellent written and oral communication skills;
- Is a good listener who asks probing, relevant questions;
- Is able to meet deadlines while producing high-quality work;
- Is comfortable to work with;
- Is flexible with respect to schedules and changing needs,
- Is patient with clients who have little statistical knowledge;
- Has experience relevant to your subject area or is sympathetic to your scientific issues;
- Understands the resource constraints; and
- Shows respect for statistical and research ethics.

Statisticians have different areas of statistical expertise, so try to find one whose skills match your technical problems. For example, a statistician who has worked primarily on experimental studies is unlikely to be versed in best methods for analyzing survey data.

It is reasonable and appropriate to ask the statistician to describe her formal training, continuing education, and previous consulting experience, such as might be presented in a curriculum vitae. You can also ask for the names of previous clients whom you can contact.

II. The First Consulting Session

In your first extended discussion, you and the consultant establish the basis of the consulting relationship. Often there is no charge for this initial, exploratory meeting, but do not assume this.

If you have not worked together before then this session is an opportunity to learn about the consultant's qualifications, experience, and way of working with people.

The consultant also learns about you, the problem you need help with, and your way of working with people. You both may be able to decide at this point whether there is potential for a satisfactory consultation. If the statistician judges that the project is outside her area of statistical expertise or that it demands more time than she can devote to it, the consultation may end here. The statistician may be able to refer you to a colleague who is more suited to your needs.

A. Introducing the consultant to the problem

Not all the issues described in this section may be resolved at the initial session, but they should be addressed and discussed. Begin by describing the problem clearly. Although you should not expect to cover all the details at this session, you should provide enough information to define the problem and provide a basis for estimating the level of effort. Expect a variety of questions as the statistician seeks to understand your research and your statistical needs. Although you might think some of these questions are not directly relevant to the statistician's role on the project, they often uncover issues with statistical implications.

B. What materials are needed?

In addition to talking about the project, most statisticians appreciate receiving written summary material. The documents should be readable and organized, and the purpose of each should be identified. You might include the following:

- Background information about the problem, including a description of the project, equipment, or procedures to be evaluated;
- A proposal, protocol, or statement of work, if one exists;
- Schematics, such as diagram or flow-chart, that illustrate important ideas and processes;

- Information about any existing database to be used.

It is not always possible or necessary to have complete information on the problem, and frequently the need for information becomes apparent in the discussion. Nevertheless, starting with legible, organized information gets the process off to a good start, saves time later and enables the consultant to give you a more realistic estimate of the time to complete the deliverables.

Once the statistician has agreed to become involved in your project, it may be worthwhile to provide prior studies, pilot data, tests, published and in-house reports relating to the problem, so that the consultant can become familiar with important issues in your research, and with the state of knowledge related to your question. For example, to estimate the needed sample size, it is crucial to have information about variability as well as an idea of how big is a meaningful effect of treatment or other experimental manipulation. Previous related research can provide a basis for estimating these.

C. What do you expect from the statistician?

You may begin the initial session with a clear idea of what you want the statistician to do for you. Alternatively, you may be completely open to suggestions about how to proceed. Usually a researcher is between these two extremes.

Even if you begin by thinking you know exactly what the statistician should do, be prepared to consider alternatives. Based on her professional judgment and your goals, a statistical consultant will likely present you with choices among valid alternative statistical approaches that may vary in scope, cost, or precision. She should also explain the ramifications of not taking her advice.

Sometimes client and statistician can define their mutual expectations completely at the initial session, other times it may take several discussions, with time between to study and to think more about the problem.

At the end of each meeting, you should ask the statistician to state what she understands about the project and you should state your expectations, to assure your mutual understanding.

During the discussion of expectations, the deliverables for the project should be specified. Deliverables may include a report of the analysis and results, the datasets created during the analysis, programming code developed to do the analysis, or attendance at meetings.

D. Preserving confidentiality is important.

It is your right to require that information derived from a consulting session be considered confidential. You should discuss this with the statistician before you proceed to discuss the problem, and obtain her agreement, in writing if desired, to comply with this requirement.

If you request, the statistician should agree not to discuss the problem with a colleague or use the data in any way without your express permission. However, a statistical consultant can provide confidentiality only within limits of the law (generally she cannot assure privacy and confidentiality from legal processes of discovery).

In addition, you should take precautions to make sure that the privacy of others is not violated in the material you provide to a statistician. This includes both human subjects

and proprietary information. Information that can link data to a specific person, e.g., name, address, employee number, should be removed and the subject identified only by a code that is unique to the study. If you are acting for an industrial client, you can remove any specific references to the client or product.

E. Financial terms.

The charge for a consultation may be set at a fixed amount for the entire project or may depend on variable factors such as time and costs. If the former, then the goals, services, and deliverables must be specified in detail in writing and agreed to by both parties before a fee can be determined.

Sometimes, the financial arrangement is a blend of these two methods. For example, the statistician provides an estimate of the total time required and is paid on the basis of hours actually worked, but may agree to a limit on the total amount.

Typically 'overhead' items, such as computers, office supplies or delivery services are covered by the hourly rate or total fee, while travel costs and meeting time are not. The latter are usually beyond the control of the statistician.

Another itemized cost might be specialized software or equipment needed specifically for your project and agreed upon in advance of purchase.

You and the statistician should agree on what is billable. Possible items include:

- Time spent in orientation to the problem,

Meetings (including the initial one),

- Telephone conversations longer than a few minutes,
- Research into finding/developing a statistical solution, and
- Responding to editor's or supervisor's review of a publication or report. (Note that preparing a publication or report is usually defined as one of the project deliverables.)

You and the consultant should also agree on when the "clock" starts running—i.e., that you now have a formal working relationship for which you have agreed to pay for services and deliverables and the statistician has agreed to provide these. Because there is often an initial phase in which the statistician is learning about the project and deciding whether to become involved, the starting point may not be obvious.

You and the statistician should make sure at the beginning that the available funds are adequate to complete the consultation as planned. Both parties should be prepared for contingencies if funding is inadequate or cut off.

Also, the project may take more time than was estimated. You should discuss how to handle this. Sometimes it is necessary to renegotiate the contract, if the scope of work changes substantially (e.g., a larger sample is obtained than initially planned, or a meeting presentation is added or deleted).

F. Schedule for payment.

This also needs to be settled at the beginning. Will you pay periodically for time worked or a predetermined amount monthly? Should the statistician bill you or will you agree to a payment schedule? If the statistician bills you, what are the terms?

G. Other considerations.

The statistician may ask your permission to cite your project as an example of a successful

collaboration (at the end of the project), to use you as a reference for future clients, or to use the study as a motivating example (with masking of proprietary details if you desire).

Will the statistician be required to travel to learn more about the project, present results, or participate in team meetings? If so, who will pay the travel expenses and how much of the transit time will be billable to the project?

If additional personnel need be employed, e.g. data entry personnel, who will pay them?

III. Responsibilities of a Statistical Consultant

As described above, a statistician's level of involvement in a project should be agreed upon at the start of the consulting relationship. A statistical consultant is ethically bound to be honest about what needs to be done to successfully complete the study, to make every effort to fulfill any agreements about her role, and to admit to limits to expertise that affect ability to provide deliverables.

A good statistical consultant takes time to learn about the project and refrains from giving quick answers to informal inquiries. Only after understanding your goals and learning about the science and data can the statistician advise you on how best to carry out your research.

A statistician should be aware of ethical and regulatory constraints, such as human subjects' protection or financial privacy laws, and verify that any aspect of the study does not violate these.

Depending on your level of statistical knowledge, you might perform the analyses yourself or have the statistician do it. The statistician should explain – in a way that is comprehensible to you – statistical concepts and methods and their implication for the project, including practical guidance on how you will implement them.

If the statistician does the analyses, she should be willing to provide details of analysis or database definition, such as coding of variables and which subjects are included in an analysis sample.

When it is time to report the study results, the statistician should guide you on what can be claimed and concluded based on the available data. In addition, the statistical consultant will probably explain assumptions of the methods used and limitations of the findings.

Remember that the statistician will work hard on the project but there are limits to what can be learned from any given study. An ethical statistician will not agree to anything less than full disclosure of methods and analysis results in any report or publication, including factors that might limit the value of the study such as errors in procedure.

A statistical consultant should not join a project unless she can expect to achieve valid results. Finally, the statistical consultant should disclose potential (financial and other) conflicts of interest and resolve them.

IV. Responsibilities of a Client

You r statistical consultant can do a better job if there is excellent communication between you and her. This helps to prevent undesirable consequences such as the statistician providing a good solution to the wrong question. You should make sure that the statistician has a good understanding of the objectives of the project by providing

relevant background information.

It is also important that the statistician understand the system from which the data arise. Always ask for feedback from the statistician to see whether your description and explanation have been understood. However, be realistic in your expectation of the statistician in terms of learning the jargon and key issues in your application area.

The client also has a responsibility to be complete and accurate in describing how the data were acquired, including any problems that occurred during data collection or deviations from the study protocol.

Any type of missing data or procedural error (such as randomizing before baseline tests verified eligibility) should be documented, as they may affect the conclusions that can be drawn from analysis results. Often, the statistician will know a valid approach for proceeding despite these issues.

Human subjects' protections, animal rights, and other research regulations should be observed.

In the interpretation of results, you should be open-minded if the data conflicts with your prior beliefs. Some of the greatest scientific breakthroughs have been from unexpected findings. In addition, remember that you may not be able generalize your study results beyond the study population. The statistician is there to help you arrive at valid conclusions based on your study results.

Finally, any publications or reports you produce out of the project should acknowledge the participation of the statistician, consistent with the value of that participation. The statistician will expect to be a coauthor on articles on which she had substantive input. However, you should not associate the statistical consultant's name with the project without explicit consent of the consultant.

V. Ethics in Statistical Consulting

A statistician should be guided by professional and scientific ethics, which promote the integrity of the data analysis and conclusions.

The results of a valid statistical analysis may not conform to the expectations or desires of the client or consultant. However, pressuring a statistical consultant to achieve a predetermined outcome may adversely affect the validity of study results as well as the statistician's credibility.

No one can guarantee that the results of an analysis will be exactly what were hoped. An expert with a thorough knowledge and understanding of statistical methods is best-equipped to establish and defend valid conclusions from the data and study design, as well as to identify and explain any limitations to the conclusions that can be drawn.

The American Statistical Association (www.amstat.org/profession/ethicalstatistics.html) and International Statistical Institute (www.cbs.nl/isi/ethics.htm) have published ethical guidelines for professional statisticians.