The Research Protocol

This chapter introduces the reader to the concept of the research protocol, and its relation to (a) planning ethically responsible research, (b) working with one's IRB, and (c) using the rest of this book to plan research and develop the protocol. It stresses the importance of using the protocol as a planning tool, not as a bureaucratic evil…a form to be tossed together at the last minute. The details that need to be considered in developing a protocol are discussed in subsequent chapters, and a full discussion of the protocol is presented in Chapter 12.

In research involving humans, as in any complex undertaking, the best way to develop an ethically responsible project is to consider systematically (in writing) the research rationale, methods, and procedures, and the steps that will be taken in response to ethical considerations. Just such a written plan…the protocol…is required by federal regulations of human research. The most effective way to develop an adequate protocol is to begin writing it when the research planning begins; thus, the investigator is reminded to think through the ethical considerations along with the methodological ones. The alternative is to treat ethical considerations as an afterthought and perhaps discover that the research plan is not workable.

2.1 WHAT IS A PROTOCOL?

The research protocol is an official account of the intended research methods and procedures, with special attention to how benefit is maximized and risk minimized, autonomy of subjects is respected, and fairness to subjects is ensured. Included is a brief discussion of the research problem and hypotheses, relevant literature, the research methods, and the investigator's background. This clarifies what is to be done, how, and why. Some other elements of the protocol (and chapters where these are discussed) include:

- Subject selection, recruitment, and justification for the number and kind of subjects proposed: Chapters 3, 4, 5, and 12.

- Benefits to subjects and others: Chapter 9.

- Risks and how these will be minimized, including risks to privacy and confidentiality: Chapters 5, 6, 7, 8, 10, 11, and 12.
Informed consent: Chapters 4, 6, 9, 10, and 12 and Appendix A.

Obtaining permission of a parent or guardian, and subjects' assent, when subjects are minors: Chapter 10.

The protocol might consist of a one- or two-page statement and a consent form, if the project is simple and involves little risk. Or it might be considerably longer. The protocol is prepared by the researcher and submitted to the IRB. It reminds the researcher of many of the elements that are essential to scientifically and ethically sound research, and provides the information needed by an IRB to carry out its legal mandate. A protocol that has been tossed together at the last minute to request IRB approval is likely both to overlook important issues and result in delay of IRB approval.

The protocol enables the investigator and the IRB to ascertain at a glance whether certain matters are handled properly. For example, is the consent statement appropriate? The protocol discusses the purpose and procedures of the research, the characteristics of the research population, the risks and benefits, and the informed consent procedure. Thus, the IRB can observe whether the consent procedure describes the risks and safeguards, the benefits, and the general nature of the research...taking into account the perspective and background of the subjects. A consent statement that overlooks the perspective and background (e.g., culture, education, reading level) of subjects is disrespectful and may adversely affect response rate and cooperation.

The IRB may examine the feasibility of the sampling plan. The protocol states how many subjects will be recruited, from where, and how, and what inducements will be offered to subjects. Does the plan call for too few or too many subjects? Is the subject population suitable to the purpose of the research? Are there concrete plans to benefit those who participate in the research? Is exploitation avoided? In research conducted in an organization (e.g., a school, hospital, workplace, recreation center), the IRB will require the written permission of an authorized gatekeeper for the researcher to approach the subjects. It will require evidence that subjects are not coerced into participating by either the researcher or the gatekeeper. Other things to include depend on the nature of the research.

In a large interview project, one ought to indicate how hired interviewers are trained, and whether they are paid by the hour or “by the head,” and why. These matters affect whether subjects are treated respectfully, the success of the sampling procedure, and the validity of the research.

Because the protocol directs the investigator's attention to problems intrinsic to the design and procedure of
the research, it is seriously recommended that the investigator begin writing the protocol in the early stages of research planning.

### 2.2 CONTROL DOCUMENTATION

Institutions are legally responsible for research conducted within them...as are researchers and their supervisors. Therefore, IRB protocols must reflect what is actually done in the research. Once the IRB has approved a protocol for a particular project, the investigator is bound to follow that procedure, or to have the desired change of procedure approved by the IRB. That is, the protocol becomes a control document, an official statement that specifies how the study is being conducted.

This document becomes a vital part of an official “paper trail” showing that the research is acceptable to a legally constituted board of reviewers. Should anyone raise questions about the project, the approved protocol is powerful evidence that the project is of sufficient value to justify any risks or inconveniences involved.

*Case 2.1: A (Fictionalized) Study of Moral Development.* Dr. Knowall interviews school children about their understanding of right and wrong. A parent who gave permission for his child to participate in the research later regards the project as seeking to change his child's religious beliefs. He calls the newspaper, the ACLU, the mayor, the school board, and the governor to complain that Dr. Knowall's research violates the separation of church and state. The university is required to respond, and proffers the approved protocol, which would be powerful evidence in any legal proceeding that the project was socially and legally acceptable...except for one thing: The researcher had slipped in a few questions about religion after receiving IRB approval. The researcher finds himself in serious trouble and without enthusiastic backing from his institution.

### NOTE

1. The research or treatment protocol is a concept and practice from medicine in which the details of the presenting problem, the patient, and the intended treatment (research) are spelled out in great detail and reviewed by appropriate supervisors to ascertain that it meets the highest ethical, clinical, and research standards. It
is developed at the outset, incorporated into the patient's chart, and followed throughout the treatment or re-
search. Unfortunately, when social scientists began to develop protocols for their IRBs, most had no such 
tradition or training. Rather than use the protocol as a tool for planning and professional consultation, many 
social scientists regard the protocol as a piece of paperwork one does for the IRB.

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