Developing a Research Protocol

The protocol format and reminders offered in this chapter combine the best of many of the forms used around the nation and will be useful even if the reader’s own institution has a specific form. An IRB may raise any questions pertinent to the specific research project, even if those questions are not specifically addressed in their particular protocol format or instructions. This chapter, and its references to the rest of the book, enable the reader to answer such questions.

12.1 SUGGESTED ELEMENTS OF A PROTOCOL

One’s individual protocol should reflect the requirements of one’s department and IRB and should contain any additional information pertinent to the evaluation of the particular project. The following protocol elements meet federal requirements and include additional features that many institutions have found useful.

1.
A cover sheet should include (a) the name and department of the principal investigator (PI), (b) his or her faculty rank or student status, (c) home and office phone number(s) and (d) address(es) of the investigator. This information enables the IRB reviewer to contact the investigator informally about questions that arise when reading the protocol, and perhaps to provide verbal approval before the formal approval is mailed. The cover sheet should also indicate (e) the project title; (f) the type of project, such as faculty research, externally funded project (with name of funder), student directed research (with name of faculty adviser, thesis, dissertation, course requirement...give course number and faculty name); and (g) the intended project starting and ending dates. It is useful to mention one’s qualifications to conduct the specified research in a paragraph or two on the cover sheet, via an attached curriculum vitae, or with the description of the methodology. The cover sheet must contain (h) the signature of the principal investigator, and if the PI is a student, (i) the adviser. Some institutions also designate departmental or school representatives to review and sign off on protocols.

2.
A description of the research, which includes the following: (a) the purpose of the research and the hypotheses to be tested; (b) the historical background of the research, referring to pertinent scientific literature (in brief, as in an abstract); (c) an orderly account of the research method, design, and mode of analysis, detailed enough that reviewers can assess scientific validity, including a fully detailed account of procedures that directly affect subjects; (d) a realistic statement of the value of the research, including both what the researcher expects to learn from the research and what value it will have for the participants and their community, the re-
search institution, the funder, or science (Research is not of value to science unless it is of publishable quality. See Chapter 9.); (e) the location of the research…specifying the exact laboratory, community, institution, and so on where various components of the research are to be performed, the reason why that setting was chosen and how the researcher happens to have access to it; (Is the researcher employed there? Did he or she do volunteer work there? Is it his or her old neighborhood or an organization to which he or she belongs?; (f) duration of the project and how this window of time coincides with such other time constraints as the duration of funding, the periods of the school year when research can reasonably be carried out in a school, the period of time before an election when voting attitudes might be examined.

3.

A description of the prospective subject population should include, where relevant, ethnic background, sex, age, and state of health. It should explain why that particular population is being used, the source(s) from which it will be obtained, and a statement of the selection criteria. If vulnerable populations are included, such as pregnant women, children, institutionalized mentally disabled, prisoners, or those whose ability to give voluntary informed consent is in question, the rationale for using such subjects should be stated. If the research is conducted in an institutional setting (e.g., a school, a club, a church, a home for the aged), written permission of the person in charge must accompany the protocol.

The expected number of subjects should be specified, and a statistical justification of the number of subjects should be provided either here or in the description of the research design. The researcher is urged to consult Kraemer and Thiemann (1987) and Lipsey (1990) for guidelines to deciding how many subjects to use.

4.

The discussion of possible risks should include inconveniences or discomforts, especially to the subject, and where possible, an estimate of the likelihood and magnitude of harm. Most IRB members are highly skilled risk assessors and take a dim view of researchers who ignore minor risks or inconveniences and blithely write “no risk.” There are many forms of risk to subjects and others connected with the research, including the investigator, the community, and the institution. These are discussed in Chapters 5 (Privacy), 6 (Confidentiality), 7 (Deception), 8 (Categories of Risk), 10 (Research on Children), and 11 (Community-Based Research).

Discussion of risks should involve both objective risks and what subjects might perceive as risks (as in Case 1.1), and should indicate what will be done to allay each actual risk or unwarranted worry. As appropriate, the researcher might describe alternative methods that could have been used to minimize risk, stating why they were rejected. For example, IRBs are always quick to urge that data be collected anonymously to prevent breach of confidentiality; however, the researcher may have good reasons to collect unique identifiers.
5. 
Discussion of inducements and benefits to the subject and others should take into account the concepts regarding benefit, presented in Chapter 9, and field research, in Chapter 11.

6. 
Freedom of subjects to withdraw with impunity is a right that must, by law, be respected. If the subject is not free to withdraw from the research at any time, the protocol should both explain why and state when the subject is free to withdraw. Pertinent details of subjects’ freedom to withdraw should appear in the consent statement.

7. 
Source and amount of compensation, if any, to be received by a subject or beneficiary in the event of injury is typically not addressed in social research protocols, where chances of injury are very small and liability for incidental injury is often covered by the university’s workmen’s compensation insurance.

8. 
Analyses of risks and benefits are to be summarized, and any risk must be shown to be substantially offset by benefits that the researcher has arranged to produce.

9. 
The informed consent procedure should be described, including how, where, and by whom informed consent will be negotiated, and how debriefing will be conducted (see Chapter 4). In Chapter 10, problems of obtaining children’s assent and parental or guardian permission for research are discussed.

The actual consent form, if any, should be attached to the protocol. If consent is negotiated orally and not documented in writing, a statement should be attached regarding the information that is to be presented to prospective subjects orally. The content of the debriefing should also be described.

10. 
Attachments…such as any letters of permission, the consent form, interview or survey questions, materials to be presented to subjects, tests, or other items connected with the research…should be attached to the protocol, if they might be pertinent to the IRB's evaluation of the project.

12.2 SUPPLEMENTAL PROTOCOL CHECKLIST

The following is a list of typical problems that IRBs encounter, and tips on how to cure them:
“Rubber stamp” signatures. Those who sign off on the cover sheet of the protocol have a legal responsibility to have evaluated the protocol for legality, clarity, accuracy, and good writing. Students dissatisfied with their formal supervision should seek other help with the protocol and the design and analysis of the research, and consult research methods texts as needed.

Failure to mention investigator qualifications. This is especially serious in the case of inexperienced investigators. This statement should be clear, specific, and relevant. It might include prior research training and experience, membership in or special knowledge of the research population, or qualifications for counseling subjects as appropriate.

Too many generalities about the purpose of the research. IRBs are suspicious of protocols that devote much space to extolling the importance of the research, but fail to describe the methods and procedures adequately.

Vagueness about research location and permission. The protocol should be specific about where the research will be performed and how the investigator got permission to do the research. It should include letter(s) of permission from the relevant gatekeepers and discussion of what the researcher has agreed to do in return for that permission.

Vagueness about sampling procedure. Arrangements for access to subjects and for sampling should be complete before submitting the protocol. The protocol should be exact in the description of the sample frame, how it was obtained, and exactly what sampling procedure will be employed (e.g., a two-phase random sample using a table of random numbers, a random sample stratified on ethnic group with oversampling of Native Americans, a convenience sample); see, for example, Babbie (1979) or Kidder (1981). If the sample frame consists of members of a private group, the IRB will want to know if the list of names is public information, and if not, how the researcher obtained that list and what permission was obtained to use it. Depending on the sensitivity of the research, some sampling strategies may pose objectionable threats to privacy; see Hartley (1982) for details.

Vagueness about the research design. The protocol should state exactly what general design or method is to be employed; for unusual procedures, it should describe any work previously done to test the procedure. Complex research designs might be accompanied with diagrams, if necessary, to show who gets what treatment and when, and when measurements are taken. For survey research, specify who and how many are to be surveyed, when and by what method they are to be surveyed, and what key cross-tabulations are planned.
For case studies, state whether it is a behavioral single-subject design or a clinical case study; indicate how the raw data will be obtained and how the case study will be derived from those data, perhaps citing a methodology text that sets forth the rules. Protocols for action research should state why the action research is called for, the specific goals, the activities that are expected to achieve those goals, and how those goals are expected to come about. The goals of the action research should be ones jointly developed with the subjects, not goals foisted on subjects.

Omission of information about the political context of the research. Often, applied social research is done because there are conflicts, problems, or disagreements between parties at the research site. Perhaps the research is done to understand something about the problem, or to intervene. It is essential that the political context of the research be described accurately in the protocol.

“Fitting the format.” Most protocol formats are designed for experimental or descriptive research, not for action or intervention research. In order to “fit the protocol,” researchers sometimes make their project look like it is an experimental or descriptive study when it is actually action or intervention research. The protocol should state clearly what the purpose of the research is, even if the protocol format seems designed for describing something else.

Ignoring risk. Most social research involves some risk, if only that a survey may ask people to think about things that will make them uncomfortable, or that the data on some subjects, were it to fall into the hands of a malicious gossip, could cause trouble for the subjects. IRBs recognize that some risk is inevitable and acceptable; what they find unacceptable is the researcher who fails to recognize risk.

In sensitivity to issues of coercion in dual-role relationships. It is often easiest to arrange to do research in familiar settings; however, this is likely to involve a dual-role relationship. For example, one might study one’s own clients, students, or employees or do participant observation research in a group of which one is a part. Or one may arrange to do research in a group where the gatekeeper takes unscrupulous advantage of the situation (perhaps coercing members of his or her organization to participate, or seeking access to confidential data in return for permitting the researcher access to the setting).

IRBs recognize that the only feasible way to do some important kinds of applied research is in a dual-role relationship. For example, a graduate student cannot easily arrange to try out a teaching intervention on someone else’s class, or to try out a therapy intervention on someone else’s patients. In such situations, however, special precautions must be taken:
• Every step must be taken to assure that subjects know that their participation is strictly voluntary...that they will lose no advantage and will fully retain the respect and goodwill of the researcher and gatekeeper if they refuse to participate.
• Subjects must have a neutral source to whom they can turn in case of problems. For example, if free counseling is offered to anyone who is upset by his or her research participation, the counseling must be available from an independent third party, not the researcher or the gatekeeper.
• Where feasible, participation should be anonymous, so that the researcher or gatekeeper does not know who participated or who did not.

A second kind of dual role is that in which the researcher is also an intervener. The researcher needs to be clear about what he or she and others consider to be his or her primary role. If the researcher is primarily an intervener...one who provides a service...then relevant other services may not be withheld from subjects.

Dual-role relationships introduce potential conflicts, which should be recognized at the outset and discussed not only with experienced members of one's IRB but also with experienced researchers who have had to work in dual-role situations.

*Using data generated by others.* When some or all of one's data have been generated by others, the IRB will want to know both the source of the data (e.g., a public archive, an individual scientist, a school or university student testing program) and who released the data and authorized their use in the proposed research. A letter of authorization may be required.

*Research on physical and physiological qualities.* Research on the effects of, say, caffeine or physical exertion may be safe for most, but not all, subjects. The IRB will want to know that the campus physician or some other medically qualified individual has reviewed and approved the research plan.

*Research that stigmatizes persons.* The researcher who is intent on helping persons who are in need of some intervention is likely to overlook the fact that research participation may stigmatize the subjects. So-called prevention research, community interventions, behavior modification programs, and research on people who already occupy a status to which stigma is attached may heighten the visibility of the these people's stigma. Every effort must be made to ensure the privacy of such individuals.

https://doi.org/10.4135/9781412985406