Methodological Appendix

We selected a nationwide purposive sample of 40 researchers to represent a range of experiences in heath-related research. The group included four researchers at UNC-Chapel Hill and 36 researchers identified through the Computer Retrieval of Information on Scientific Projects (CRISP) database — an electronic database of federally funded biomedical research projects conducted at universities, hospitals, and other research institutions (http://crisp.cit.nih.gov/ Accessed 10/27/05.) We sent emails to PIs of 36 seemingly suitable projects, asking them to participate in our study. Non-responses with followed up with two additional emails. Each time a researcher refused to consent to participate in the study, or did not respond to the email requests, we identified additional projects and PIs. PIs were then emailed and sent follow-up emails where necessary. This procedure was repeated until informed consent to participate in our project was obtained from 36 researchers.

Data Collection

The interviews for this project focused on the broad area of investigators' experiences with and attitudes toward the IRB-dominated human subjects protection system. The questionnaires consisted of 18 specific questions, with probes for several of them. However, the interviewer used an unscructured approach. In general, the interviewer (Dr. Moss) let the answers evoked by her initial questions shape her subsequent ones (Schumacker et al, 2005). She was flexible with regard to the particular wording and order of the questions, those questions she did and did not ask, and when and how she pursed specific topics raised by the respondent (Patton, 2002). Before selecting the sample, we pilot tested our interview instrument on four biomedical researchers who are colleagues of this project's PI (Dr. Moss) at UNC-Chapel Hill. These four individuals have varying degrees and kinds of experiences with IRBs. We then revised the instrument based on the pilot test feedback.

The interviews were conducted by telephone. Dr. Moss typed respondents' answers during the interviews. All of the interview data were entered into a qualitative software database (Atlas.ti. version 5.0 Scientific Software Development, Berlin, Germany) for coding, management, and analysis.

Data Analysis

First, we (Dr. Moss and Professor Burris) developed a coding scheme to identify the major emergent themes. Next, we used the coding scheme to independently code three randomly selected interviews, one with a clinical researcher and two with non-clinical researchers. Then, we talked to reconcile coding discrepancies and revise the coding scheme.

Next, Dr. Moss and a research assistant used the new coding scheme to independently code four more randomly selected interviews, two with clinical researchers and two with non-clinical researchers. They then met to reconcile coding discrepancies and finalize the coding scheme. Next, they entered the coded transcripts into the qualitative database and coded all 40 transcripts. Finally, Dr. Moss and Professor Burris reviewed the coded transcripts to further discriminate interview passages into categories that subsequently became the final themes discussed in the paper.

Final Telephone Interview

Hello, my name is (deleted for manuscript reviewers).. I hope you recall that you agreed to participate at this time in a research project I am conducting for the Robert Wood Johnson Foundation. To remind you, the project addresses the rules governing the protection of human subjects in research. It is not about changing the rules. Instead it is a pilot study of different kinds of investigators' reactions to the rules. I am interviewing 40 researchers who do health-related research about their experiences with and attitudes towards the rules. All interview responses will remain confidential. Identifying information will not be cited in reports of the research or permanently retained.

May I proceed with the interview? _____

(If Yes, Say)
Thank you. I will now begin.

(If No, Say)
Would you prefer participating at a different time? _____

(If Yes, Say)
When would be a better time for the interview? _____

Thank you. I look forward to interviewing you at the time you suggested.

(If No, Say)
I understand that you do not wish to participate. If you do change your mind and would like to participate, please call 1-800-243-0887.

RESEARCH QUESTIONS

The first several questions are brief ones aimed at finding out just a little about you and your research.

Would you briefly describe your position at (insert name of institution the person works for).

Would you please briefly describe the sort of research you do. (Probe about whether the research involves conducting any clinical interventions with human subjects.)

Currently, to which IRB at (insert name of institution the person works for) do you submit most of your protocols?

Thank you.

The next set of questions are aimed at finding out approximately how much time and effort go into different kinds of IRB protocols. In order that you have something specific to think about, I am going to ask you to respond in terms of any two projects that you can think of for which you prepared and submitted protocols to your current IRB. I then will ask if your answer with respect to these two projects is more or less representative of how much time and effort you put into preparing your IRB protocols.

4a. With respect to the two projects you are thinking about, did you prepare the IRB protocols, did a research assistant or someone else prepare them or was there some combination of effort?

4b. Is this representative of how you generally prepare IRB protocols? (If no, probe about why not).

5a. With respect to the two projects you are thinking about, did you request exemptions? (If yes, probe about why the respondent asked for exemptions, and whether the requests were approved?)

5b. (If respondent requested exemptions, ask Is this representative, if so why and if not why not?.

6a. With respect to the two projects you are thinking about, did you request expedited reviews? (If yes, probe about why the respondent asked for expedited reviews and whether the requests were approved.)

6.b. (If respondent requested expedited reviews, ask) Is this representative, if so why and if not why not?.

7a. With respect to the projects you are thinking about, did it take a great deal of time, a medium amount of time, or not very much time to prepare the protocols and respond to the IRB and could you please elaborate. (Probe about whether the respondent used strategies for minimizing the time and, if so, what they were. Also probe about whether the IRB process involved delay and/or if the respondent ran into serious problem because the IRB held him/her up.)

7.b. Ask if this is representative and if not representative, probe about why not. Also, ask whether the person spends more or less time now filling out IRB protocols and why.

8.a. With respect to the two projects you are thinking about, did the IRB ask you to make changes in your protocols and, if so, what sorts of changes?

8b. Ask if this is representative and if not representative, probe about why not.

9a. With respect to the two projects you are thinking about, were requirements about informed consent a problem or issue and, if so, in what way?

9b. Ask if this is representative.

10a. With respect to the two projects you are thinking about, can you briefly summarize your opinions about the extent to which the IRB was helpful or unhelpful. (Probe about which aspects were helpful, which aspects got in the way, and whether you think the costs outweighed the benefits or the benefits outweighed the costs.)

10b. Ask if this is representative and if not representative, probe about why not.

The next set of questions does not address the two projects you have been addressing. Rather, the questions are concerned with whether and how the IRB process in general has influenced your research.

11. Has your past experience with the IRB process changed how you view the ethics of research and, if so, how? (Probe about whether respondent takes ethical issues into account in any way because of his/her experience with IRBs).

12. Has your past experience with the IRB process affected your choice of research designs? (Probe about whether respondent does or does not decide to use certain designs because they are or are not ethical or because using them would or would not create problems with the IRB).

13. Has your past experience with the IRB process affected your choice of study populations? (Probe about whether respondents are more or less likely now to work with "vulnerable" populations, whether respondent does or does not decide to work with certain study populations because doing so is or is not ethical or because doing so would or would not create problems with the IRB.)

13. Has your past experience with the IRB process affected how you go about obtaining informed consent? (Probe about whether respondents are more or less likely now to use different methods of obtaining informed consent than previously, and if the respondent does use different methods of obtaining informed consent whether this is because of ethical reasons or because of whether he/she is avoiding problems with the IRB.)

14. If the person has changed anything as a result of the IRB ask, Do you feel that the changes you have made in response to the IRB have been positive, negative or neutral for you or your work and would you please elaborate on why?

I have several final questions.

15. Is there anyone else in your professional life, besides an IRB, who is concerned about the ethics of your research with human subjects, (probe about peers, journal editors, department chairs or deans, other supervisors).

16. Has HIPAA affected how you design and conduct research and if so in what way?

17. Has there been a scandal or some kind of blow up related to human subjects research at your institution or another institution which has affected what the IRB has required or how it has behaved and, if so, could you elaborate?
18. Do you have anything else you wish to add?

Codes and Definitions of Codes

Code	*Subcode*	Definition
Direct--		Researchers who directly interact with human subjects:
	Intervention	Does research testing drugs, devices or medical or behavioral interventions, clinical trials
	Nonintervention	Conducts surveys or observations or other forms of data collection not entailing a physical procedure intervention
Secondary		Researchers who obtain and analyze secondary data
Tissue		Researchers who obtain and analyze material of human origin such as tissues or specimens
IRB positive		Respondents mentions something about IRB that is positive
IRB negative		Respondent mentions something about IRB that is negative
IRB other		Respondent makes a descriptive comment about IRB, but comment is neither positive or negative--i else.
Ethics		Respondent mentions something about ethics
CYA		Respondents engage in defensive behavior, protecting the institution
Time		Respondent mentions the amount of time it takes to deal with issues related to the Common Rule
Multi-institution		There is a mention of multi-institution studies
Informed consent		Respondent mentions informed consent
International research		There is a mention of international research
Exemption		Respondent mentions something about exemptions
Expedited		Respondent mentions something about expedited review
HIPPA		Respondent mentions something about HIPPA
Suggestions for improvement		Respondent makes a suggestion for improvement
Protocol		Respondent discusses who prepares IRB protocol
Unsure		Flagged for review.
Burdensome		Respondent mentions the burdensome aspect of dealing with issues related to the Common Rule
Full Review		Respondent refers to an IRB full review.
University Researcher		Respondent works in a university
Non-university treatment & research facilities		Respondent works in a treatment and research facility not part of a university
Free-standing research center		Respondent works in an organization that does not provide treatment and is not part of a university
Research focus		Respondent mentions something about focus of his or her research

Patton, M. Q. (2002). *Qualitative Research and Evaluation Methods* (3rd ed.). Thousand Oaks: Sage Publications, Inc.