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The Invisible Hand in Clinical Research: The Study Coordinator's Critical Role in Human Subjects Protection

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Over the past decade, the number of clinical trials registered with the Food and Drug Administration (FDA) has increased dramatically.[1] The business of clinical research has become more diverse, involving academic institutions, clinician-researchers in community settings, pharmaceutical companies, and contract research organizations. This growth has been accompanied by increasing concerns about the ethical conduct of research.[2] Much of this concern has been directed to procedural issues including institutional review board (IRB) review, data monitoring, and informed consent forms. However, the protection of human subjects cannot be achieved by relying solely on procedural safeguards. There are more nuanced issues related to recruitment and retention of subjects, and to the process of informed consent,[3] that are generated during the interaction between study staff and subjects. It is only through an examination of these relationships[4] that one can more fully define and understand the challenges of protecting subjects in research.

Study coordinators are at the center of the clinical research enterprise. In collaboration with principal investigators, they assist with protocol development, write consent forms, recruit subjects, explain the study to and obtain consent from subjects, coordinate with relevant hospital/clinic units, collect and maintain clinical data, and serve as the main contact person for subjects during a trial. One recent survey identified 128 different activities performed by study coordinators.[5] Studies have shown that adding a coordinator to a research team significantly improves subject recruitment numbers,[6] enhances subject retention,[7] and increases general study efficiency.[8]

Much of study coordinators' added efficiency is a result of their central position in clinical research activities. They see themselves as interpreters or liaisons, especially in their relationships with principal investigators and subjects, representing the study to subjects and subjects to fellow researchers, clinical staff, and to relevant institutional and external (e.g., federal government, financial sponsor) actors. Each relationship may require a different role, but more commonly, the study coordinator position requires that one relationship encompass several roles. Of particular interest is how clinical study coordinators reconcile the roles of caregiver and researcher. Some reports focus on study coordinators' successful combination of these two roles,[9] while others emphasize their inherent incompatibility.[10]

Despite literature that chronicles their skills and efficiencies, surprisingly little systematic information is available regarding the impact of the study coordinator on the protection of human subjects. In fact, when study coordinators have been in the limelight, it has often been as objects of rebuke. For example, approximately 19 percent of investigators receiving FDA warning letters in 2000, and more than 37 percent in 2001, were cited for failing to

supervise their trials.[11] In an anecdotal analysis of twenty of these incidents, almost half of the investigators blamed study coordinators for their citations.[12]

Study Coordinators and the Ethical Conduct of Research

Given this ambiguous profile, a key question to answer is the extent to which study coordinators shape the ethical conduct of clinical research and how their multiple roles affect the protection of subjects. To understand these issues, we conducted interviews with study coordinators, asking them to respond to scenarios that presented a series of potential dilemmas. We recruited participants from three types of work settings — an academic medical center, a federal research institution, and private organizations. Our underlying hypothesis was that a variety of orientations toward patient care and clinical research might engender different responses.

Focus group interview study

The study was approved by the IRBs at the University of North Carolina School of Medicine (UNC) and the National Human Genome Research Institute. Informed consent was obtained from all focus group participants. Pilot interviews with thirteen study coordinators at UNC identified key issues. Because these issues proved potentially complex and contingent, we selected focus group discussions, designed to foster conversation about specific topics among people with similar backgrounds, as our method of data collection. The ability to assess participants' reactions to statements by peers, as well as the type of language and phrasing used, give focus groups their special purchase on social interaction.[13] To accommodate potential sensitivity about our questions, an issue raised in pilot interviews, we selected a vignette-based approach, a projective technique that allows respondents to discuss issues without direct personal references.[14] The design of these focus groups was more structured than is usually the case.[15]

The first set of vignettes elicited information about study coordinator skills and roles. The groups were presented with two different job advertisements with three potential candidates for each, and were asked to decide who would be the best for the job. Participants also commented on contrasting statements about the compatibility of nursing with clinical research (see Box 1).

The second set of vignettes posed questions about two hypothetical study coordinators recruiting subjects for a hypertension outpatient study and an oncology trial for patients whose disease had failed to respond to conventional therapies. The moderator led the group through a series of questions about the following topics: (1) appraisal of subject motives; (2) recruitment methods; (3) responses to subjects' hope for direct medical benefit in a trial: (4) responses to subjects' desire to withdraw from a study; (5) pressure from investigators and study sponsors to increase enrollment numbers; and (6) difficulties involving other staff in recruitment and subject follow-up (see Table 1).

In 2000, we conducted seven 90-minute focus groups: three at the UNC, a public academic medical center with a mix of patient care and clinical research; two at the Warren G. Magnuson Clinical Center (NIH), a government organization dedicated to research; and two

private focus groups with participants from the Research Triangle Park area of North Carolina and the Washington, D.C. area. These private sector participants worked as freelance consultants or as employees of research foundations, private research institutes, and contract research organizations; one private sector participant was employed full time by the research arm of a private clinic. There was a total of forty-five participants; 68 percent had nursing backgrounds. Other backgrounds included social work, genetic counseling, general baccalaureate, and public health, with education levels also varying from high school to doctoral degrees (see Table 2).

Informed consent was obtained from all participants. Discussions were audio-taped and transcribed. Analysis of the transcripts led to a codebook of twelve index codes (see Table 3), each with dozens of subcodes produced through an iterative process that involved several readings of the text and revisions of the codes. Each of the investigators was involved in code development and validation, with three of us (Davis, Hull, and Henderson) coding and reconciling the seven transcripts in teams of two, and bringing disagreements back to the larger group. Transcripts were coded using a qualitative analysis program, NUD.IST version 5.[16]

Analysis of the focus groups suggests that study coordinators have a central position, with complex relationships, role expectations, and the potential for conflict among the roles.

Unless otherwise noted, all quoted material in this article is attributable to study coordinators who participated in our study.

The Study Coordinator Position in Clinical Research

Multiple skills and relationships

The study coordinator position requires a wide variety of skills, including nineteen general skill types, and twenty-five subcategories (see Table 4). Most frequently mentioned were: hands-on clinical skills; the ability to advance research goals using a variety of research-related skills; psychosocial skills; communication skills; and complex organizational skills including managing the protocol, functioning as a team member, and coordinating with outside units. Intrinsic to several of these skill sets is the study coordinator's ability to identify necessary relationships with others, inside and outside the research team, and to forge and sustain them. A number of different relationships were identified; the most frequently cited relationships were with supervisors, including principal investigators, and patient-subjects (see Figure 1).

Patient care background

For some, nursing and research are “a wonderful match … because you really get to utilize your nursing background.” In our job application vignettes, the nursing candidates were most often selected because their hands-on skills, clinical expertise, and psychosocial skills were identified as excellent preparation for the job. If not trained as nurses, coordinators need to be patient-oriented. As one participant noted, “If you're going to be dealing with patients at all, you can't totally disassociate yourselves with [sic] what a nurse needs [to know], because at some point you're going to leave the page and talk with a human.” In

contrast, a nursing background can be seen as detrimental when it interferes with the research agenda. A private sector group noted that many nurse study coordinators have problems with protocols that deviate from the standard of care. As one participant in the group said, “I have great nurses working for me and [sometimes] I could pull my hair out because I can't get them in the research mode.”

The Three Advocacies

As one of the participans noted, “One criterion for a study coordinator is… the ability to balance all of the issues from the clinical trial side and the medical patient care side, and translate both to the principal investigator, who mostly is medically-oriented, and to the patient involved in the study.” Focus group participants consistently described their position in terms of complex and potentially conflicting obligations to various parties. They identified three critical roles: (1) patient advocacy; (2) subject advocacy; and (3) study advocacy (see Table 5). One role is often identified in contrast with another. Participants discussed the moral dimensions of these conflicts. Their discussions focused on relationships; only occasionally did they explicitly describe conflicts as *ethical* issues.

Patient advocacy

All focus group participants identified patient advocacy as their primary responsibility. Contrasting this with the investigator role, one participant noted: “You're still the patient advocate. You know, you have to think about what your priority is. Enrollment, I think, is the [principal investigator's] priority, but that's not necessarily your priority.” Study coordinators often think in terms of a patient's interests and needs. This commitment to the patient's welfare translates into an advocacy for the patient that follows the subject into the study,[17] and remains a central role for the study coordinator during the study and perhaps thereafter. The salience of the patient advocate role may affect which patients the study coordinator talks to about the study, and whether the study coordinator encourages or discourages interest in participating. Another participant noted that the study coordinator has to be very careful because the patients “look to you as an advocate for them …. They [easily conclude that] you're recommending [what they should do].” Patient advocacy was reflected in the participants' explicit use of the term “patient advocate” as a metaphor, and in comments about “mothering” or “taking care of” patients.

Subject advocacy

Study coordinators are vital to the investigator's ability to enroll and retain subjects. The role as subject advocate emerged in descriptions of the recruitment process, though study coordinators typically continue to use *patient* rather than *subject* terminology. Subject advocacy promotes an informed decision to participate in research: it entails the subject gaining an understanding of the study's purpose, of the nature of voluntary consent and the corresponding ability to withdraw from the study, and that declining to participate will not affect their current health care in that setting. One participant summed up a common description of the role, in terms of risk and subject safety: “I think that the subject, if the coordinator is doing the job as it should be done, sees the coordinator as an advocate, understands… that there are risks, but that the coordinator is there to be tuned in to anything

that might, you know, indicate that something is going on that might be harmful to the subject." Although investigators may certainly advocate for subjects, coordinators contrasted their role with the investigator's role, including access to information that investigators do not have: "You're the one listening and dealing with the patient…. They're not there." For subject advocacy, the metaphor used by study coordinators was "lawyer," to protect the rights of this individual and to remind investigators of the subject's right to withdraw from the study. Subject advocacy does not survive the end of participation in the study, but the relationships acquired may be satisfying personally, or may be instrumental in future recruitments.

Study advocacy

Study coordinators are hired to advocate for the study. Participants discussed study advocacy in terms of advancing the research goals, and gathering valid clean data via good recruitment and retention of subjects. They also emphasized responsibilities of the enrolled participants: "It's important for subjects to also understand that [commitment]." Beyond that, study coordinators expressed a need to believe in the value of a study. Without that, the job is more difficult, even undesirable. Advancing the study may also advance the investigator and study coordinator's professional careers. Therefore, there are personal stakes, as well as scientific outcomes. The metaphor used here was "policeman of the protocol," and also "teacher," because often the study coordinator trained others, including other staff members, in the conduct of the study. Study advocacy does not survive the conduct of the study, but good performance can be professionally advantageous.

Balancing the Roles

Because the three advocacies have different objectives, they must be balanced. Although there are instances when the advocacies are synergistic, the more common result of balancing is one of potential conflict. One advocacy may hinder the advancement of another. For example, when a coordinator carefully maintains an objective stance as a *subject* advocate, this may conflict with the role of *patient* advocate, advising patients who are dependent on the study coordinator for guidance. Likewise, *patient* advocacy can be burdensome in the course of *study* advocacy, as described by one participant: "It is very, very important to be very objective, so patients understand that if they do enroll in a study, we're not saying that this is going to fix you or cure you. This is research and we're learning from it, you know. We'll do everything to make sure that you're safe … and [we will stop] if we need to, but I think that's where [I get into] conflicts because patients are just so hopeful…. You want patients to be positive, but you need to be realistic too."

Balancing can be difficult. As noted by one participant: "It takes a while to develop a balance so that you can be the patient advocate but you can also be the researcher, and when you have to be tough, and when you have to say to the doctor that they've had enough…. A lot of it is experience." And this balancing is necessary throughout the course of a study. As early as protocol development, where the study coordinator assists the investigator in creating a study design reasonable for its subjects, and during the study's implementation, via recruitment, screening, and enrollment, the study coordinator balances concerns for the patient, the subject, and the study. After enrollment, the balancing of advocacies continues

as the study coordinator addresses data collection and retention issues such as compliance, managing side-effects, and withdrawals.

We examined how study coordinators balanced their multiple roles in two ways—from a general question about the care giving and researcher roles, and a specific question in the cancer trial vignette about how one should respond to a hopeful patient subject. When the participants considered the contrasting quotes from the literature (see Box 1), they provoked a discussion about the general compatibility of nursing and clinical research. Participants argued that the study coordinator position must include both the *caring* component of nursing and the *detached* analytical gathering of knowledge that is fundamental to research. "[You have to be clear] that you're doing research and there's a point to it and its not clinical care, but it includes [clinical care]. It includes … being empathetic and education and all the things nurses do in a clinical setting. However, there's a specific point and you have to be somewhat… rigid to get that objective."

Response to the hopeful patient subject vignette illustrated more particularized relationships and skills. The need for "balancing hope and realism," was consistently identified as the "tough part of the job." These study coordinators struggled with their perception that they must be realistic with patients, an aspect of all three advocacies, but without destroying the therapeutic value of patients' hope, a mainstay of patient advocacy. They worried about not misleading patients who could "easily get the wrong impression," since "just being referred gives them hope." "When patients are willing to try anything," study coordinators say they have to protect patients from themselves, and this "makes it kind of hard on the coordinator." Responding to the hopeful subject, as patient advocates, they want to encourage patients' hope but not take advantage of it. As study advocates, they recognize the value of hope in encouraging subject participation; and as subject advocates, they move away from both of those positions to one of neutrality, providing information but without unduly influencing decision-making.

The picture would be incomplete without recognizing the parallel tension between hope and realism in members of the research team as well. As patient advocates, study coordinators themselves hope that the patient will benefit from participation in a specific study, or at least will benefit from better care while "on study." Coordinators' "belief in a study," as study advocates, evinces their hope that the study will work, or that altruism is beneficial for patients. Researchers' hopefulness in individual benefit and in the successful outcome of the study is tempered by subject advocacy with its "hope neutral" realistic focus on key features of research participation: that patients choose to participate for their own reasons, that benefit is not promised, and that subject safety measures are in place.

Influence of workplace setting on balancing roles

We found surprisingly little variation in description of the study coordinator role across the three different work settings. There were, however, some differences in degree of emphasis on one advocacy versus another. For instance, when describing the challenge of balancing hope versus realism for hopeful subjects, the UNC study coordinators emphasized patient advocacy. The NIH coordinators focused on both subject and study advocacy, such as patient safety and dose-tolerance; while the private sector sites emphasized good study results.

Private sector participants further advised keeping a certain distance from subjects' hopefulness, to listen and “then go on your way.” Perhaps not surprisingly, study advocacy appeared to be more fully articulated in the NIH and private sectors, settings that are research-oriented and have a more clearly defined study coordinator role, hierarchy, and support system.

The Invisible Hand in Clinical Research

Focus group participants across all settings described themselves as advocating for patients, patients-turned-subjects, and research. While not representative of all study coordinators or research organizations in general, the finding of similar roles across carefully selected case comparisons such as these —when differences are expected by design—is compelling.[18]

Previous literature about study coordinators has acknowledged the tension between the dual role of researcher and caregiver.[19] Our results suggest that, in fact, study coordinators have several roles, and more importantly, that these roles must be balanced. Balancing the three roles heightens the potential for conflict as the study coordinator promotes the interests of each part of the triad: the patient, the patient-turned-subject, and the study. Clearly, there are times when one advocacy must advance and the others retreat, and deciding which one to focus upon and which ones to subrogate is the major ethical challenge of the study coordinator position.

The constant movement between different roles, coupled with the potential for influential long-term relationships, also increases the complexity of the position and reinforces its centrality. *Coordinator* is often noted to be the best descriptor of the job, following a string of labels denoting tasks that range across different relationships and skills, from study conception to follow-up.[20] While recent literature has also focused on the efficiencies of the position,[21] study coordinators still tend to be invisible players in much of the general clinical research and ethics literature.

Why have study coordinators been neglected in the literature on the protection of subjects in research studies? One answer is that the job has been considered an assistant's position, with little authority or autonomy. A profession is often defined by a group's ability to control the application of a body of knowledge and establish training programs that award jurisdiction over that knowledge to recipients.[22] In contrast, the study coordinator is an occupation in transition, lacking agreed upon training requirements or job criteria. Neither the creation of the research nurse subspecialty,[23] or the establishment of a clinical research coordinator certification program by the Association of Clinical Research Professionals (ACRP), has resulted in an independent professional identity for study coordinators. New National Institutes of Health guidelines do require all “key personnel” involved in research to certify receipt of ethics training.[24] With the rapid proliferation of excellent clinical research training courses, the focus is on the investigator; there is no certainty that study coordinators will be included as key personnel and therefore required to receive training in ethical issues related to human subjects protection.

In fact, the challenges we describe that are raised by study coordinators' different advocacies resonate with much that has been written about the dual role faced by physician-

investigators.[25] While our purpose was not to examine the similarities of these two roles, the fact that the potential role conflicts seem similar only serves to reinforce the importance of the study coordinator role for the protection of human subjects.

Moreover, because of their central position and their commitment to balancing the three advocacies, study coordinators are uniquely placed to further the goals of human subject protection. The study coordinator is the person with whom subjects interact the most, and the one most able to identify their needs and employ necessary procedural safeguards. Often, challenges that raise ethical issues are most apparent to study coordinators, yet their particular perspective may go unnoticed or be misunderstood. Such misunderstanding may be cast as blame for ethical lapses in the study, an age-old issue for study coordinators starting with Nurse Rivers, a “scientific assistant” in the Tuskegee syphilis study,[26] and persisting today in commentary about FDA warning letters, as described in the introduction.[27]

The findings that study coordinators face challenging issues related to human subjects protection demonstrate why it is critical that study coordinators be included in research ethics training programs. Indeed, the focus group discussions revealed participants' keen interest in research ethics education, and in a forum to discuss their ethical issues. These results also suggest that evaluating the adequacy or inadequacy of the protection of human subjects cannot rely solely upon procedural safeguards such as IRB review, data monitoring, or informed consent forms. It must include explicit recognition of the study coordinator's role. Further research to test our findings regarding the role of study coordinators in recruitment, consent, and retention is also indicated. Through greater recognition of the invisible hand in clinical research, we can better address the complex issues of human subjects protection.

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References

1. Hovde M, Seskin R. Selecting U.S. Clinical Investigators. Applied Clinical Trials. 1997; 8:34–42.
2. Department of Health and Human Services, Office of Inspector General. The Globalization of Clinical Trials: A Growing Challenge in Protecting Human Subjects. Sep. 2001 OEI-01-00-00190available at <http://oig.hhs.gov/oei/reports/oei-01-00-00190.pdf>
3. Annas GJ. Reforming Informed Consent to Genetic Research. JAMA. 2001; 286:2326–28. [PubMed: 11710901]
4. King, N.; Henderson, G.; Stein, J. Beyond Regulations: Ethics in Human Subjects Research. Chapel Hill: University of North Carolina Press; 1999.
5. Papke A. The ACRP National Job Analysis of the Clinical Research Coordinator. The Monitor. Winter;1996 :45–53. at 46.

6. Cooper J, Lomax J. The Role of the Research Nurse in Clinical Trials. British journal of Clinical Practice. 1989; 43:167–68. [PubMed: 2590633] Isaacman DJ, Reynolds EA. Effect of a Research Nurse on Patient Enrollment in a Clinical Study. Pediatric Emergency Care. 1996; 12:340–42. [PubMed: 8897540]

7. Good M, Schuler L. Subject Retention in a Controlled Clinical *Task*. Journal of Advanced Nursing. 1997; 26:351–55. [PubMed: 9292370]

8. McKinney J, Vermeulen W. Research Nurses Play a Vital Role in Clinical Trials. Oncology Nurse Forum. 2000; 27:28–29. at 28.

9. Grady C. Ethical Issues in Clinical Trials. Seminars in Oncology Nursing. 1991; 7:288–96. [PubMed: 1775780] Di Giulio P, et al. Expanding the Role of the Nurse in Clinical Trials: The Nursing Summaries. Cancer Nursing. 1996; 19:343–47. [PubMed: 8885481]

10. Ecklund DJ. Establishing a Research Coordinator Network: The Birth of an Idea. Journal of Nursing Administration. 1999; 29:20–25. [PubMed: 9921145] Hicks C. Nurse-Researcher: A Study of a Contradiction in Terms? Journal of Advanced Nursing. 1996; 24:357–63. [PubMed: 8858441] Johnson JM. Clinical Trials: New Responsibilities and Roles for Nurses. Nursing Outlook. 1986; 34:149–53. [PubMed: 3635037]

11. Gamache V. Chasing Away Phantom Investigators. CenterWatch. 2001; 8(no. 11):1, 5–9. at 1.

12.

Id.

13. Stewart, DW.; Shamfasani, PN. Focus Groups: Theory and Practice. Newbury Park, California: SAGE Publications; 1990. Krueger, RA. Focus Groups: A Practical Guide for Applied Research. 2d. Thousand Oaks, California: SAGE Publications; 1994.

14. Merton, RK.; Fiske, M.; Kendall, PL. The Focused Interview: A Manual of Problems and Procedures. 2d. New York: The Free Press; 1990.

15. Entwisle B, et al. Designing Points of Convergence: Methods for Integrating Qualitative Approaches into Quantitative Analysis. 2002 unpublished.

16.

N5, QSR International Pty Ltd, Melbourne, Australia.

17. Annas, GJ. Standard of Care: The Law of American Bioethics. New York: Oxford University Press; 1993.

18. Ragin, C. The Comparative Method: Moving Beyond Qualitative and Quantitative Strategies. Berkeley: University of California Press; 1987.

19.

See Grady, *supra* note 9; Di Giulio et al., *supra* note 9; Ecklund, *supra* note 10; Hicks, *supra* note 10; Johnson, *supra* note 10.

20.

See Di Giulio, et al. My Role as a Research Nurse Coordinator. Critical Care Nursing. 1990; 12:39–44. supra note 9; D.A. Seguin.

21.

See Papke, *supra* note 5; Cooper and Lomax, *supra* note 6; Isaacman and Reynolds, *supra* note 6; Good and Schuler, *supra* note 7; McKinney and Vermeulen, *supra* note 8.

22. Abbott, A. The System of Professions. Chicago: University of Chicago Press; 1988.

23.

See Johnson, supra note 10; Hubbard SM, Donehower MG. The Nurse in a Cancer Research Setting. Seminars in Oncology. 1980; 7:9–17. [PubMed: 7367902]

24. National Institutes of Health. Required Education in the Protection of Human Research Participants. Notice OD-00-039 (June 5, 2000) (revised August 25, 2000), available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00039.html>

25. Churchill LR. Physician-Investigator/Patient-Subject: Exploring the Logic and the Tension. journal of Medical Philosophy. 1980; 5:215–24.Katz J. Human Experimentation and Human Rights. Saint Louis University Law Journal. 1993; 38:7–54. [PubMed: 11656326] Slatkoff SF, Curtis P, Colcer

A. Patients as Subjects for Research: Ethical Dilemmas for the Primary Care Clinician-Investigator. Journal of the American Board of Family Practice. 1994; 7:196–201. [PubMed: 8059623] Miller EG, Rosenstein DL, DeRenzo EG. Professional Integrity in Clinical Research. JAMA. 1998; 280:1449–54. [PubMed: 9801009] Elks ML. Conflict of Interest and the Physician-Researcher. Journal of Laboratory Clinical Medicine. 1995; 126:19–23. [PubMed: 7602230]

26. Reverby SM. Rethinking the Tuskegee Syphilis Study: Nurse Rivers, Silence and the Meaning of Treatment. Nursing History Review. 1999; 7:3–28. [PubMed: 10063364] Reverby, SM., editor. Tuskegee Truths: Rethinking the Tuskegee Syphilis Study. Chapel Hill: University of North Carolina Press; 2000.

27. See Gamache, *supra* note 11.

Box I

Compatibility of Nursing and Research: Contrasting: Quotes

"(T)he research process and the nursing process are very similar. The researcher, like the nurse, assesses and reassesses needs, develops and implements plans, and gathers data to promote better patient care." *	"Research, irrespective of the methodology adopted, calls for an entirely different set of core values from those demanded of nursing, requiring detachment rather than caring concern, objectivity rather than subjectivity, hard nosed analysis rather than intuition, pro-activity rather reactivity. Consequently, directives to conduct research may implicitly be directives to relinquish the essential characteristics of nursing." **

* D.A. Seguin, "My Role as a Research Nurse Coordinator," Critical Care Nursing, 12 (1990): 39—44, at 43.

** C. Hicks, "Nurse-Researcher: A Study of a Contradiction in Terms?," Journal of Advanced Nursing, 24 (1996): 357—63, at 358.

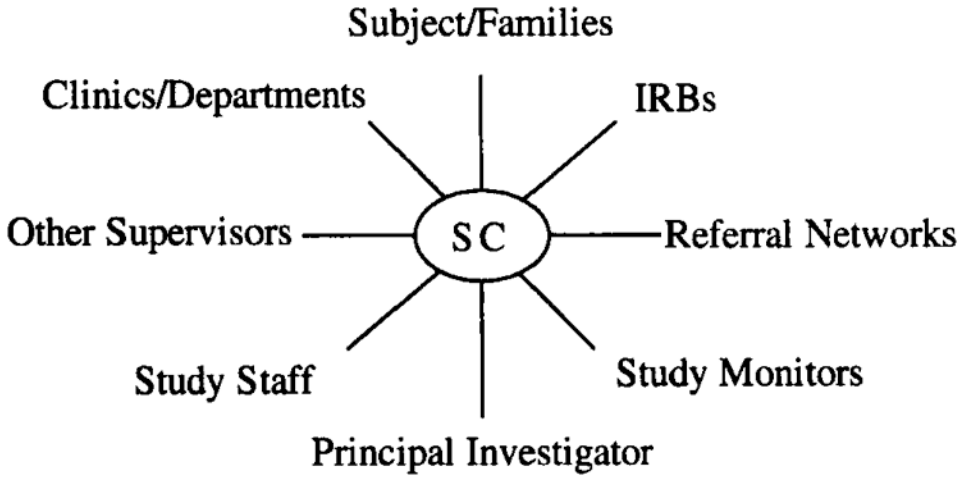

Figure 1. Study Coordinator's (SC) Central Position

Table 1

Focus Group Vignettes

Focus Group Vignettes on Study Coordinator (SC) Job Applicants	
Job#l: Federally funded multicenter melanoma study, with fifty inpatient subjects, followed for 5 years	• Registered nurse, with 6 years experience in adult critical care nursing, coordinator experience in cardiology • Pharmacist, masters level, with 15 years hospital experience, 6 years in cancer care • Social worker, masters level, with 3 years experience in oncology and bone marrow transplantation
Job #2: Industry funded asthma study, with 80 subjects, comparing inhaler regimens over 3 years	• Respiratory therapist in university asthma unit, experience in asthma education • Clinical nurse specialist, masters level, specialist in asthma clinic, prior experience with chronic obstructive pulmonary disease and cystic fibrosis • Graduate student in biostatistics
Focus Group Vignettes on Study Coordinator (SC) Recruitment Dilemmas	
Study #1: Phase II outpatient study, recruitment comparing two medications for hypertension	• How to recruit two clinic patients (new vs. current patient)? • What aspects of study or subjects influence recruitment? • What do subjects look for in this kind of study? • When a subject expresses hope, what does SC say? • What happens if others (clinic staff) aid in recruitment efforts? • Principal Investigator worries about enrollment, but subject wants to withdraw? • What if sponsor offers cash incentive to increase enrollment? • What other incentives are important to SCs?
Study #2: Phase I study of treatment for patients whose lung cancer failed to respond to standard therapy	• How to recruit two clinic patients (new vs. long time patient)? • What aspects of study or subjects influence recruitment? • What do subjects look for in this kind of study? • If SC knew subject in another trial, would that matter? • When a subject expresses hope, what does SC say?

Table 2

Focus Group' Participant Characteristics

SITES	UNC	NIH	PRIVATE	TOTALS
Number of Groups	3	2	2	7
Number of Participants	23	12	10	45
Male/Female	2/21	0/12	1/9	3/42
Nurse/Non-Nurse	14/9	10/2	7/3	31/14
Mean Age	38	46	41	41
Age Range	(21-51)	(29-60)	(28-56)	(21-60)
Mean Total Years as SC	4	9	7	6
Range of Years as SC	(0.5-12)	(3-20)	(2.5-15)	(0.5-20)
Highest Degree: High School	1	0	0	1
2 Year Nursing	2	0	0	2
3 Year Nursing	4	0	0	4
BS in Nursing	3	1	3	7
Other BA/BS	6	1	2	9
Masters in Nursing	3	8	2	13
Other Masters	4	2	2	8
Doctorate	0	0	1	1

Table 3

Study Coordinator (SC) INDEX Codes

1	SC Professional Background
2	Types of SC skills
3	SC job/role characteristics
4	Research subject characteristics
5	Study characteristics
6	Subjects' motivation to enroll in study
7	SC recruitment approaches/strategies
8	SC retention strategies and issues
9	SC motivation to do recruitment/job
10	Prior and current relationships
11	Challenges faced by SC
12	Areas self-identified by SC where education is needed

Table 4

Study Coordinator Skills

1	Prior clinical experience
2	Prior research experience
3	Technical/hands-on clinical skills
4	Clinical research skills
5	Teaching skills
6	Psychosocial assessment and counseling skills
7	Organizational/planning/management skills
8	Communication (with public, others, etc.)
9	Ability to balance competing issues
10	Identification of “ethical” problems
11	Patient advocacy skills
12	Subject protection/advocacy skills
13	Ability to advance research goals
14	Honesty
15	Objectivity (non-biased)
16	Detachment
17	Creative problem solving
18	“Multifaceted preparation”
19	Respect for people (includes sensitivity/patience)

Table 5

Study Coordinator Advocacies

	Patient Advocacy	Subject Advocacy	Study Advocacy
Primary Commitment	Patient's welfare	Rights and welfare of individual as research subject	Advancing research goals; gathering valid, clean data via good recruitment and retention of subjects
Duration of relationship with patient-turned-subject	Before, during, and/or after	Before and/or during a study	Study specific
Metaphors	“mothering” “taking care of”	“lawyer”	“policeman of protocol” “teacher”
Selected Quotes	“Among the different roles in research…one of the major roles is as a patient advocate, and I don't think you divorce yourself from that because you are doing some kind of research related to a particular hypothesis. And if you are, then you should not do research, I don't think.”	“I always approach people, even people I know well, from that sort of objective point or view and kind of try to work with them, giving them all the facts and then let them collaborate with us. See what they think they can tolerate and that might be best for them. So 1 feel you can offer this to somebody that you know well and that's been through it, but just being as clear, crystal clear that you are not trying to seduce them into it, that there are good and bad points to being in a study.”	“Once you make the decision that you like this protocol, you think there's some value here, you think it's something you want to do. then you have a commitment to the protocol, and you shouldn't have conflicts…. You need to be in a position to defend it honestly and comfortably.”
Example of Balancing:			
Coordinator's response to the hopeful patient-subject	Recognizes the therapeutic value of patient's hope	Tries to be hope-neutral, providing accurate information for decision making	Recognizes that hope may encourage participation
Coordinator's own hopefulness	Hopes that the patient will benefit from participation	Tries to be hope-neutral, focusing on voluntariness, no promise of benefit, and minimized risk	Hopes that the study will be successful or that altruism will benefit the subject

"(T)he research process and the nursing process are very similar. The researcher, like the nurse, assesses and reassesses needs, develops and implements plans, and gathers data to promote better patient care." *	"Research, irrespective of the methodology adopted, calls for an entirely different set of core values from those demanded of nursing, requiring detachment rather than caring concern, objectivity rather than subjectivity, hard nosed analysis rather than intuition, pro-activity rather reactivity. Consequently, directives to conduct research may implicitly be directives to relinquish the essential characteristics of nursing." **

* D.A. Seguin, "My Role as a Research Nurse Coordinator," Critical Care Nursing, 12 (1990): 39—44, at 43.

** C. Hicks, "Nurse-Researcher: A Study of a Contradiction in Terms?," Journal of Advanced Nursing, 24 (1996): 357—63, at 358.