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# Day for Night: Facilitating Collaborative Solutions in the Pursuit of Approval for Human Subjects Research

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*University of Tennessee - Knoxville*

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To the Graduate Council:

I am submitting herewith a thesis written by Joseph D. Shearer entitled "Day for Night: Facilitating Collaborative Solutions in the Pursuit of Approval for Human Subjects Research." I have examined the final electronic copy of this thesis for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Master of Science, with a major in Counseling.

Robert F. Kronick, Major Professor

We have read this thesis and recommend its acceptance:

Joel F. Diambra, Marianne R. Woodside

Accepted for the Council:

Carolyn R. Hodges

Vice Provost and Dean of the Graduate School

(Original signatures are on file with official student records.)

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Marianne R. Woodside

Acceptance for the Council:

Linda Painter

Interim Dean of Graduate Studies

(Original signatures are on file with official student records.)

DAY FOR NIGHT:  
FACILITATING COLLABORATIVE SOLUTIONS IN THE PURSUIT OF  
APPROVAL FOR HUMAN SUBJECTS RESEARCH

A Thesis

Presented for the  
Master of Science  
Degree

The University of Tennessee, Knoxville

Joseph D. Shearer

December 2006

## Dedication

This thesis is dedicated to my mentors, Dr. Charles L. Thompson, Dr. Robert Kronick, Dr. Joel Diambra, and Dr. Marianne Woodside, and my family, Steve Shearer, Danita Shearer, Jessica Clements, and Maliha Haider, who believed in me and supported me unconditionally.

## Preface

For first-time researchers, the prospect of executing a Master's thesis can be as exciting as it is daunting. Students pursuing skill sets in the helping professions may view their thesis not just as a way to contribute to their field of study and do something that will be helpful to society, but also as a way of contributing to treatment agencies that allow fledgling researchers access to human subjects. Unfortunately, good intentions, energy, and a positive outlook may not be enough to bring an idea for research to fruition. One need only begin the process of seeking Institutional Review Board (IRB) approval for the use of human subjects and other necessary approvals to uncover the dizzying necessity for coordination among many parties that must be in place for a study of any complexity to be executed. Just as a clock seems simple at a glance but reveals, upon further scrutiny, an engineer's masterful efforts at integrating many moving parts and principles, so does the thesis study seem a natural and simple thing before the apprentice researcher uncovers the many principles and moving parts that must collaborate and work together harmoniously to create the illusion of effortlessness. Though difficult to navigate at times, the IRB process is absolutely necessary as evidenced by studies that predated the IRB and were infamously harmful to participants such as the Stanford Prison Experiment (SPE) and the Tuskegee Syphilis Experiment. This paper discusses the lessons learned by two student researchers in their efforts at such collaboration. It is written in hopes of identifying the unanticipated barriers that might keep other students from hearing that satisfying and deceptively simple ticking as they aspire to make a contribution of their own.

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## I. The Necessity of Institutional Review Boards

The necessity for IRB approval for the use of human subjects is virtually undisputed. In the interest of keeping research participants safe from harm, it is the field standard to hold researchers accountable for their use of human subjects and prevent them from performing, intentionally or otherwise, unethical behavior with those subjects by requiring them to attain the approval of an IRB before beginning data collection. Infamous examples such as the Stanford Prison Experiment (SPE) and the Tuskegee Syphilis Experiment remind us of the potential to do harm if our research is not closely refereed. Zimbardo (1998) found that “emotionally strong” students “suffered acute psychological trauma and breakdowns” when they began to fulfill the roles of prisoners in a mock prison for the purpose of his study. Lombardo and Dorr (2006) theorize that flaws in medical education helped to make the Tuskegee Syphilis Experiment, which studied the horrifying effects of untreated syphilis in African-Americans, “the most infamous American example of medical research abuse.” In both examples, researchers worked diligently toward their ultimate endgame and likely believed that their research would yield a significant contribution to their fields of study. Emphasizing the contribution, however, de-emphasizes the crucial process of pouring over a study’s nuances to be certain that no harm is done.

There seem to be at least two clearly defined sides to every argument, no matter how irrational one side or the other may seem. The SPE and Tuskegee Syphilis Experiment are well documented and discussed in the literature as examples of the necessity for IRBs, but examples of IRBs being negative or perhaps hindering research



are elusive. In fact, I was unable to find even one formal argument against the necessity for IRB approval for the use of human subjects. At least in the literature, people seem to agree that IRB approval is absolutely necessary so that participant safety is protected as much as possible. This is reasonable, of course, and I believe it to be the case.

Furthermore, I found the IRB process to be very helpful and doubt that my study would have gotten far without it. However, I was interested to know if any argument existed that challenged the necessity for IRB approval and decided to use an Internet listserv read by hundreds of researchers and helping professionals to see if such an argument exists. I posted the following question to the listserv: “Can anyone help me find a journal article or book with an argument against the necessity for IRB approval for qualitative research? Something that sums up the controversy would help me write my master's thesis and I noticed that this issue has been discussed on this listserv. Arguing for the IRB is easy...” The immediate response came from those who were incredulous that I would ask such a question. People seemed baffled as to why I would ask this question and called for clarification as to my reasoning. One responder declared that they “would be amazed” if I could find “such an argument,” while another wondered, “why any researcher would not want to go through the IRB process.” One responder asked if my question was “some sort of joke,” suggested that my questions be screened from the listserv, and invited me to seek “any argument as to why we should stop at red lights at traffic intersections.” At this point, the discussion deteriorated into talk of whether or not there are foolish questions and why I should have been more specific with my question. I seemed to have struck a nerve with my question, which perhaps suggested a belief that IRB approval is not necessary where human research subjects are concerned. The answer to my question, it

seemed, was a resounding “no, and you are foolish to have asked.” The literature and informal words of the community of helping professionals seem to be clearly united in the assertion that IRB approval is not only necessary but also desirable.

## II. On the Same Page: The Batterer Intervention Study

In the spring of 2006 I began work as a Therapist Intern in a Batterer Intervention program as part of my efforts to fulfill the internship requirement of my Mental Health Counseling Master's Degree program. Commonly referred to as anger management, Batterer Intervention is more psycho education than therapy and is intended to encourage male/female relationships based on equality so as to stop domestic violence. Clients are almost always court-ordered to attend. It was my responsibility to track attendance, co facilitate intervention classes, perform intake/assessment interviews and orientation meetings with new clients, and spend time in court speaking with men who had been referred to our program. I immediately noticed a number of problems with the program.

I quickly noted the overt stains of "bad blood" between our program and others offering the same services. I learned that another program in town was coordinated by my predecessor who had been fired from a position that included many of my current responsibilities. My supervisor spoke of him often and negatively, criticizing him for straying from the Duluth Model used in our groups and being dangerously supportive with the men. The Duluth Model is markedly different from traditional therapy, since the victim of domestic violence is considered to be the client while the batterer, with whom practitioners have direct contact, is viewed as a student whose behavior must be changed to protect the client. Batterer/students must be held accountable for their actions and be encouraged to view their behavior critically and specifically without minimizing their behavior, denying it, or blaming others for their actions. This is a confrontational practice which is not at all conducive the unconditional acceptance, warmth, understanding, and

empathy of the traditional therapeutic relationship. My predecessor disagreed with the approach and empathized himself right out of the job.

I was struck by the failure of these professionals to collaborate under the same theoretical approach, but I came to a similar and more disturbing revelation as I started to attend the groups. Duluth groups confront domestic violence almost exclusively. I do not evaluate the focus of the groups as negative or positive, but have yet to meet a batterer for whom domestic violence was the only difficulty. Indeed, participants in the groups were quite human in that they experienced a wide range of issues from drug and alcohol related issues to personality disorders, to psychotic disorders and everything in between. Many sought therapy outside of the groups at this agency and others and that therapy was, as therapy tends to be, supportive and featuring warmth, empathy, understanding, and unconditional acceptance in the interest of the positive therapeutic relationship. Batterers, no matter how insidiously they victimize others, often view themselves as victims and blame the real victims for the consequences of their violent and controlling behavior. One day, a participant would speak individually with a supportive therapist who agreed that the participant had been victimized by his victim and the criminal justice system in general. The next day, the same participant would be confronted by us who insisted that he was the one whose behavior was in question. As if therapy is not confusing enough, this contradiction confused participants to no end and fueled heated discussions in the groups as facilitators argued for the Duluth point of view.

Having been encouraged by my professors to make a lasting contribution to my internship placement, I finally saw my chance. I would write my Master's thesis with the same integrationist spirit that drove the work of Hubble, Duncan, and Miller (2001) who

found many diverse models of psychotherapy to be equal in efficacy and theorized that this efficacy is accounted for by the common factors that unite them. I would find common ground between the Duluth Model and models more appropriate for individualized therapy so that I could argue for a model or models of therapy to be used individually with group participants, which would not contradict the domestic violence intervention. I would record the sessions of one of the intervention groups and use what Dick (2005) describes as a thematic analysis to generate theory from data, or grounded theory, to draw out similarities between Duluth and established models of psychotherapy. It seemed simple enough at the time, but I had yet to pry the clock-face back and see the many moving pieces. Once I did, it seemed that a film, rather than a clock, would provide a better metaphor for what I found.

François Truffaut's celebrated film *Day for Night* is a film within a film. In the opening scene, a man walks out of a subway station, through a crowded street, and confronts another man by approaching him rapidly and slapping him in the face. The scene appears simple and natural as people go about their business with little effort and the protagonist strides purposefully to his confrontation. Then, after a pause, the action stops and the camera pulls away to reveal that the street is a movie set surrounded by cameras, microphones, and a crew of professionals. As the filming stops, the actors stop their purposeful movement and mill around aimlessly as they listen to the director call out corrections and criticisms. The scene is then filmed again, but the voice of the director can be heard this time as he instructs actors to speed up, slow down, and address other nuances that will contribute to the realistic feel of the scene. The illusionary simplicity of the scene is peeled away by the revelation that a complex and coordinated effort of many

different entities is necessary to create that natural and effortless sense. This revelation is possible only through the perspective of the director, who, through the course of the film, defines his role as one who goes to great lengths to facilitate the coordinated effort between the many entities that make the project possible. These entities include actors, producers, crewmembers, and others, all who work toward a different, and sometimes conflicting, set of goals. It is as if the director is the only person involved in the project that has the end result, the ultimate endgame, in mind. Truffaut's film offers a striking metaphor for research or coordination for any complex goal. The principal investigator is much like the director, in that it is the responsibility of the principal investigator to advocate for the common ground between the entities involved in the research study so that combined effort brings about the ultimate endgame. Barriers of collaboration arise when an entity will not coordinate their efforts because they must instead advocate for an objective that is more important to them than the project as a whole. In the case of research with human subjects, these barriers can actually be quite positive. An IRB's refusal to approve a study when a research proposal does not clarify specific risks to potential participants, for example, is a positive contribution to the research even though it temporarily halts the principal investigator's momentum to being collecting data. A good director sees to it that the interests of the necessary collaborators are satisfied so that coordinated effort can resume. This requires diligence on the part of the director, since he or she must understand the interests of the entities he tries to bring together for a common goal. Truffaut (1973) acknowledges this diligence saying, "A director is someone who is constantly asked questions, questions about everything. Sometimes he has the answers, but not always." The barriers to collaboration that I faced were often

positive and in the interest of protecting the interests of potential subjects and the agency. At the time I faced them, however, they seemed short-sighted and counterproductive. Sometimes I had the answers, but not always.

When I first approached the coordinator of the Batterer Intervention Program I met my first barrier to collaboration. I explained the idea for my study with enthusiasm, but he frowned and patiently went over the differences between intervention and therapy. He insisted that use of the Duluth model is not therapy and any comparison between the two would only confuse the issue. Instead, he suggested that I write a thesis paper explaining the differences between intervention and therapy. He also encouraged me to approach the facilitator of the group I wished to observe immediately to make sure she was not opposed to my study. It was the first time I entertained the idea that someone might be opposed to the project, but not the last. Wasn't I trying to do something that would be helpful to the agency? I thanked him for his input and silently resolved to come back to him later with a better explanation of what I hoped to accomplish. I then approached the facilitator of the group with a similar sales pitch. Her reaction was much more dubious than that of the program coordinator. She frowned and suggested that I would never be able to acquire informed consent from each group participant. She further informed me that I would not be allowed to use the time allotted for the group meetings to seek informed consent from the participants. She then encouraged me to leave her office. I was too surprised to be disappointed. Were these helping professionals deliberately trying to discourage my efforts at improving their program? The camera had begun to back away as the illusion of simplicity was revealed to me.

I started filling out my application for IRB approval and my idea became much

clearer. One day during court, I leaned over to the program coordinator and handed him my application. "Look this over," I asked him, "and tell me what you think." He turned the pages, scanning over the words as I held my breath and awaited his reaction. After a few moments, he began to nod and grin. "This is excellent," he breathed quietly as he read over the form, "outstanding." He turned to me with fire in his eyes and a grin from ear to ear as he enthusiastically endorsed the idea, saying that it would offer a huge contribution to the agency as well as to batterer intervention in general. Then he asked me if he could show my form to the judge. I stammered my endorsement even as he stood, grinning, and called out, "Your Honor, may I approach the bench?" I soon found myself again holding my breath as a judge read over my research proposal. He read every word of the paper before looking at me and smiling broadly. I breathed a sigh of relief as his words of praise poured out. He told me that the idea was a great one and that it would help the wheels of justice turn efficiently. He said that it was much too complex for a Master's thesis and praised me for taking on what seemed to him to be doctoral level work. He made me promise to share my results with him and I left the courtroom beaming.

With the program coordinator on my side, it was easy to win over the group facilitator. He went to her and once he had described my study in his own terms he soon had her nodding and grinning with the rest of us. She agreed to let me use some of the group's time to acquire informed consent from the men and offered to help me in any way she could. As I left her office for the second time, however, the program coordinator mentioned that I would have to get approval from the agency's CEO before I could collect data. That seemed simple enough. If the program coordinator, group facilitator,



my professors, and a judge were on my side, surely the CEO of the agency would see eye to eye with me as well.

The program coordinator's supervisor informed me that I could not contact the CEO directly, but would first have to speak with the supervisor of the supervisor of the supervisor of the Batterer Intervention program. This woman was very busy, but eventually met with me after two weeks of trying to schedule an appointment. When I met with her, I brought the program coordinator with me as well as my newly reworked research proposal. In no time, she was grinning and nodding and agreed with us that the study would make a meaningful contribution to the agency and anyone using Duluth for their batterer intervention groups. She promised to take my application to a meeting of the agency's leadership, present it to the CEO, and let me know whether or not the agency would approve my study.

Two weeks passed. During this time, my communications with supervisors and supervisors of supervisors were met with encouragement to wait and be patient. My application would be shown to the CEO soon, not to worry. All the while, my mentors at the University were as supportive as they were insightful and were of tremendous help. At their encouragement, I contacted a representative of the IRB to help me figure out how to acquire informed consent for the study. Surely not every member of the group would agree to participate in the study. How, then, would I be able to record the groups and use that data for my study? The artful solution was proposed by one of my mentors and endorsed by the IRB representative: I could record the groups, transcribe the recordings, destroy the recordings, and then strike any information from that transcript that had come from someone who had refused to participate in the study. In this way, I could record

groups including some men who had declined participation in the study without using their information. This victory was an important milestone to me, but the pleasure of finding a solution to the problem of informed consent was short-lived. I was told that the CEO of the agency would be out of town and would not meet with the agency's leadership for another two weeks. I became concerned that, at this rate, I wouldn't have time to collect data and write the paper in time. Spring had rapidly become summer, and I hoped to spend the summer collecting and analyzing data so that the fall could be dedicated to putting the finishing touches on my results and discussion before the defense in November and subsequent graduation in December. If I spent the rest of the summer being told to wait, then I may not have time to finish the project. I called my supervisor and plead my case to her. She promised to plead my case to the agency's leadership, if not the CEO, and get back to me. Within a few hours, I heard back from her. My research proposal would be reviewed in the next few days and I would receive a response. In a few days I did.

I was approached by the supervisor of the supervisor of the supervisor of the Batterer Intervention program. Where before she had been all smiles and enthusiasm, she now walked toward me with the apologetic frown of one who bears bad news. "I spoke with the CEO," she told me, "and I'm afraid we cannot approve a study that does not first have IRB approval from the University." My heart sank. I explained that the final research proposal must contain a letter of approval from the agency. I seemed to be caught in a stagnating catch-22 and began to feel quite frustrated. I all but pleaded with the woman, but she would not relent. I resolved to approach my professors and the IRB at my University for help.

My mentors at the University came up with a solution that the IRB representative agreed to: In the event that the IRB found my proposed study to be satisfactory, with the exception of approval from the agency providing access to the human subjects to be used, the IRB would give me a letter of conditional approval to present to the agency. If the agency would then approve the project and provide me with a letter of approval to present to the IRB, then the IRB would provide me with a letter of approval to present to the agency.

After weeks of waiting, I was thrilled to feel as if I was back in control and set to refining my research proposal and collecting the necessary signatures so that I could submit it to the IRB, which I did. The IRB responded quickly with a list of issues that needed to be addressed before they would provide their conditional approval. I was relieved and excited when I saw the list of things they wanted me to address, since I believed that I had already addressed them, however inadequately. My language in the proposal had not been clear enough, so all I would need to do was refine and clarify the proposal and I would have my conditional approval. Members of the IRB appeared to disagree in their response to my proposal. One reviewer described my research proposal as "a very well constructed protocol for a qualitative study," while another lamented that his "primary concern is the overall fuzziness of this proposal, its methods, and potential contribution."

As I worked to clarify my language, which was very helpful to me in that I came to understand the project more deeply, I found that the summer had passed. The IRB would not meet again until September 20<sup>th</sup>. I had less than three months until I would have to defend my thesis. The reality of time constraints became overwhelmingly

apparent. The agency had taken over two weeks merely to tell me that they would not approve my study. How long would it take them to give me a letter of conditional approval once they received the University's letter of conditional approval? Would the agency give me approval at all? What if the IRB decided that my proposal was still unclear and called for a second revision? How long would that take and how long would I have to wait for the IRB to meet again? Could I bring it all together and execute the study in less than three months? Perhaps I could have, but the risk was too great. If any of the actors or producers involved in the film I was so desperately trying to direct continued to delay my collection of data, albeit for positive, necessary, and helpful reasons, I would not be able to graduate on time and would have to enroll for an extra semester to see the project completed. With a very heavy heart, I spoke with one of my mentors at the University to see what my options were.

My Major Professor brushed my negativity aside, insisting that I had ample information with which to write a thesis. My efforts to conduct the study would be the subject of my study. I would write about the nonevent, the barriers that had stood between my project and I and the lessons I learned from successful and unsuccessful efforts to overcome them. These lessons would contribute to Counselor Education, in that fledgling researchers could learn from my mistakes, successes, and revelations. My thesis would be a study of a study. He explained that a similar project had already been completed and earned considerable renown among film fans: François Truffaut's *Day for Night*.

### III. Methods

As I worked to gain approval to use the members of the batterer intervention groups as participants in my study, I met a doctoral student with a similar goal. Ron Montana (pseudonym) wished to record interviews with members of the batterer intervention groups for the purpose of his dissertation. He has also worked as a facilitator of Duluth Model batterer intervention groups. Since Ron and I had been seeking approval from the same agency and the same IRB to use the same population for our research, it seemed that Ron was in a unique position to explain what had and hadn't worked for him. Perhaps Ron ran into the same problems I had and would be able to offer suggestions. Ron is a middle-aged Caucasian male. He was also chosen because he expressed interest in the project and was willing to talk. Furthermore, Ron is very articulate and intelligent, so I knew that he would be a good candidate for a phenomenological interview since he would be easy to understand.

I sought IRB approval to engage Ron in a phenomenological interview and analyze the transcript of the interview as if seeking Grounded Theory. I received approval quickly to interview this single subject. I interviewed Ron and then returned to him with the results of my analysis to ask for feedback and make sure that my proposed results were correct.

Riessman (1993) explains that "Investigators do not have direct access to another's experience. We deal with ambiguous representations of it- talk, text, interaction, and interpretation." Lester (1999) describes a phenomenological interview as being intended "to identify phenomena through how they are perceived by the actors in a

situation” and is well suited for “surfacing deep issues and making voices heard.” With Ron, I would use the phenomenological interview to gain access to his perceptions and then offer my own representation of those perceptions as accurately as possible. It is also important to note two key requirements for participants in phenomenological research. First, they should be people who are willing to talk. Second, they should be articulate people who are easy to understand, such that it will not be overly difficult for researchers to be certain that they understand the participant’s perceptions. As stated above, Ron met these requirements well.

For the purpose of my interview with Ron, I decided to begin with one request: Tell me about your experience of working toward gaining the necessary approval to use adult human subjects for your doctoral dissertation. After this question had been posed, I responded to Ron with short phrases composed of his own words to encourage him to continue speaking. For example, if Ron were to say, ‘I wanted to record a conversation with a participant,’ I would respond by saying, “You wanted to record a conversation, say more.” During the hour interview, I responded to Ron in this way in order to encourage him to continue speaking about his efforts to gain the necessary approvals for his research.

When the interview with Ron was finished, I transcribed the audio recording to text. I then read the text multiple times in search of themes so as to begin analyzing the transcript as if seeking Grounded Theory. Glaser and Strauss (1967) explain that, to seek grounded theory, one thematically evaluates a textual database to identify variables and their interrelationships. I searched the transcript for themes and other information that might be relevant to my efforts at explaining and simplifying the approval process for

fledgling researchers. When I believed that I had identified themes in Ron's words, I circled sections of text and rewrote those circled sections in another document. Glaser and Strauss (1967) call this process "coding." I then read that document to be sure that I had compiled evidence for the themes I believed that I had defined. I then wrote a third document in my own words that explained these themes. Glaser and Strauss (1967) refer to this as "memoing." When I believed that my analysis of the transcript had enabled me to understand Ron's experience and perspective, I wrote up a summary of my findings. Glaser and Strauss (1967) explain this part of the process as "writing up." I then met with Ron a second time. In this member check, Ron confirmed that I had accurately communicated his perspective and experience in the summary.

#### *Trustworthiness of the data*

To be certain that the data I presented in the thesis was accurate, I had to execute a member check with Ron. I did this by meeting with him a second time to show him exactly what I intended to include in the paper from the interview with him and I asked him whether or not he found my representation of his words to be accurate. Ron confirmed that my representation was absolutely accurate and claimed to be pleased by my representation of his perspective and experience.

After the member check, I presented the data to my thesis committee during the defense meeting so as to collaborate with them and determine if they found my data to be an accurate description of Ron's perspective and experience to the best of their knowledge. The members of my thesis committee confirmed that this data was accurate to the best of their knowledge.

*Limitations*

Lester (1999) describes “bracketing” as identifying “taken-for-granted assumptions and usual ways of perceiving.” Before a phenomenological interview, it is standard for the researcher to engage in bracketing by speaking with others about the predicted content of the interview so that the interviewer is able to identify his or her assumptions and usual ways of perceiving as related to the predicted content of the interview. This is done so that the interviewer will be able to avoid errors in interpreting the data based on his or her predispositions. Hopefully, an interviewer who is aware of his or her own assumptions will be more able to avoid the danger of allowing those assumptions to influence his or her interpretation of the data. In this way, the interviewer is better able to understand and communicate the perspective of the subject and avoid allowing biases to cloud the picture.

I did not engage in bracketing before speaking with Ron. It would have been helpful if I had, since Ron and I had had such similar experiences and I was therefore likely to agree with him wholeheartedly without being aware of my biases.



#### IV. Results

The interview with Ron confirmed my hypothesis that he and I had had similar experiences in seeking approval to use court-ordered batterers as research subjects. Ron's statements about his experience seeking these approvals can be divided into four themes that describe his perspective: Qualitative research focusing on batterer intervention is needed, researchers must specifically address what the IRB asks for, collaboration and compromises are necessary to gain approval, and the IRB is necessary, but unrealistic expectations can make helpful research impossible.

##### *Qualitative research focusing on batterer intervention is needed*

According to Ron, batterer intervention is largely derived from information gathered from the victims of domestic violence, not the perpetrators. Ron explained that over the past 30 years, it was necessary to demonize batterers so that new laws could be written to help protect victims. Now, however, we do not have a clear idea as to the efficacy of the Duluth model interventions, which are the predominant approach to batterer intervention. It is Ron's view that men who have completed batterer intervention programs should be interviewed to determine whether or not the intervention was helpful in changing their violent behavior to nonviolence. Ron's experience as a group facilitator in the intervention groups has led him to believe that some men gain nothing from the groups, while others are "profoundly changed by the experience." For this reason, he claims to have no expectations for the outcome of his proposed study.

*Researchers must specifically address what the IRB asks for*

Ron emphasized the use of IRB application templates provided by the IRB on their website that specify what they require to be addressed in the forms. These templates describe the information that must be provided in each section of the form, which helps applicants clearly explain how they will address the IRB's regulations. He described these templates as "tremendously helpful" and likened them to his work on government contracts. Ron explained, "I worked on government contracts where we've had to take government specifications and turn them into... what we're going to do to satisfy the specification. You get really attuned to each line that's in there and how to respond to it." Ron went on to say, "If you don't give them what they want, they aren't going to take it. That's a lesson of life. The authority has what they want you to give them. Life is a lot easier if you give it to them."

*Collaboration and compromises are necessary to gain approval*

The biggest problem Ron has encountered thus far concerns confidentiality. He no longer facilitates intervention groups, but has a colleague who does. Ron would like to invite his colleague's clients to participate in his study. Participants in Ron's colleague's intervention group have signed a form stating that they agree to be contacted by the group facilitator after their group experience has ended. Ron wished to contact them directly by obtaining their contact information from the group facilitator. He believed that this would be permitted, since the participants had agreed to be contacted as a follow up to their group experience, but the IRB refused. In the eyes of the IRB, Ron would have violated client's confidentiality since he would have learned their identities by obtaining their contact information from the group facilitator.

The IRB suggested the following solution to this problem. The group facilitator would contact the participants and ask them to contact Ron anonymously if they were interested in participating in the study. Ron frowned and expressed his distaste for this idea, saying, "I felt, and everyone I talked to agreed, that that would result in a sample of zero." Ron believes this because he knows something from his work with batterers that the IRB does not: that, "There's no way that any of these men would, out of their own curiosity and interest in bettering the world, go out of their way to contact some researcher they've never met." Ron explained why he believes that the batterers are extremely unlikely to go out of their way to contact him, saying, "...the majority of them will have this thing in the back of their head that I'm from the university, I'm part of the authority, I'm part of the group that had them arrested that forced them into those groups, the system that's in opposition to their life."

Ron, with the assistance of his professors, came up with a compromise. He proposed to the IRB that the group facilitator call the participants and ask them if it was acceptable for Ron to contact them. If they agreed, the facilitator would give the participant's contact information to Ron and he would contact them. Ron described the IRB's reaction to this idea as "kinda noncommittal," but he claims he was given permission by the IRB to at least present this idea in his next application.

*The IRB is necessary, but unrealistic expectations can make helpful research impossible*

During our interview, Ron mentioned the Tuskegee Syphilis Experiment as an example of why "the need for the IRB is clear." In another example of the necessity for the IRB, Ron mentioned that the infamous Unibomber, Ted Kozinski, was involved in an experiment during his college experience that was poorly refereed and did psychological

harm to him. “Imagine taking a paranoid schizophrenic and putting them through one of these [harmful] experiments,” Ron mused, “[their] contact with reality is kinda limited to begin with, and you’re going to push them over the edge.”

Ron does not deny that the IRB is necessary, but laments that if they do not agree to his proposed compromise for contacting the potential participants for his study, then he will have to abandon the study altogether. “There’s an epidemic of women being abused by their partners,” he asserted, “and we are trying to do something about it and we have no clue as to whether or not we are doing any good. I consider it a pretty horrendous social problem that we are struggling with and here’s an opportunity to gain some information as to where or not we are doing any good.”

Why would the IRB suggest that the group facilitator contact the potential participants and ask them to then contact Ron to participate in the study, when it seems clear to everyone else involved that this course of action will surely mean that the study will fail? Ron offered a few explanations. If his study fails because the IRB insists that he rely on potential participants to take the initiative to contact him themselves, then “it would just be a matter of a complete lack of understanding on their part of what these people are like. If you’ve only ever worked in a university environment, you’ve never worked with somebody who’s a depressed alcoholic who beats his wife! And if you have you didn’t know it. They are a different category of people.” Ron offered another explanation for the rigidity of the IRB’s rules, saying, “The problem is that they want to drive the probability of being sued down to zero and I think that’s unreasonable.” He went on to say that, “I think that some balance is needed between the probability of a lawsuit and the probability of getting useful knowledge for society.”

Ron is preparing a new proposal for the IRB. He hopes that he will be able to reach a compromise that will allow him to contact potential participants directly. If such a compromise cannot be reached, Ron believes that he will have no choice but to abandon his study as I did.

## V. Discussion

### *Clarity*

The most pronounced of my mistakes was lack of clarity. What seemed to be resistance to the study was often born of ignorance since I had failed to articulately clarify the inner workings of the project. For example, the program coordinator and group facilitator seemed to initially meet my idea with disapproval, but vigorously endorsed the study once I had filled out the research proposal and showed them the specific workings and intentions of the project. Therefore, I caution against approaching any entities that will be necessary collaborators in a study without first being prepared to show them a clear, written proposal for that study. A strictly verbal proposal for something as complex as a research project is ill advised, since it is likely to sound incompetent, incomplete, and clumsy, emphasizing the ultimate end game and neglecting the nuances that represent the interests of the necessary collaborators. As I noted above, the group facilitator first denied me access to the group to seek informed consent, but then agreed to allow me to use the group's time for this once she had seen and understood the written proposal. I do not know why she initially denied me access to the group, but I take responsibility for this since my improved clarity seemed to lay her fears to rest and ensure her cooperation.

The research proposal I turned into the IRB would likely have been approved had it been clearer. Indeed, many of the issues the reviewers called to be addressed were issues that I believed I had addressed already. Plain, clear language that intimately addresses the sections of a research proposal is advised at the risk of de-emphasizing the ultimate end game. Research proposals that have already been approved can provide an

example.

Ron Montana also emphasizes the need for clarity. According to Ron, researchers should look to the IRB for specific guidelines, especially application templates that specify what information and courses of action will satisfy the IRB's requirements for approval.

*Initiative and collaboration*

Though data was never collected and the study was abandoned, there were many successful instances of collaboration. The best of these was the coordinated response to the problem of attaining informed consent to record meetings of a group of participants that were likely to include individuals who had refused to participate. How could I record if even one member refused to participate? Through the coordinated effort of the IRB, my professors, and myself, each of the entities involved were able to collaborate to find a solution that was satisfying to everyone. The suggestion was made by one of my professors that I propose to collect data in the following way. I would record the sessions, transcribe the recordings, destroy the recordings, and then strike from the transcription any information coming from a group member who had declined to participate in the study. Both the agency and the IRB agreed that this would be acceptable. My professors and I would be able to collect data and move forward toward the ultimate endgame and the IRB and agency could be satisfied that I would collect no data from participants who had declined to participate. The problem would not have been solved without input from each entity and the input from each entity could not have been integrated without my efforts to do so and initiative to collect that input. When questions arise, I encourage posing them to each collaborator so that the final answers to those questions are truly

final in that they represent the interests of each entity, allowing progress to continue.

Furthermore, explaining questions or problems to each entity involved allows collaborators to help solve a problem they may not have known of. For example, I approached my supervisor when I first became fearful that there would not be time to collect data if I waited for the CEO to return and read my proposal. My supervisor then advocated for the project within the agency's leadership and was able to get a response about approving the study weeks before that response had been promised. My supervisor had not been aware of my time restraints, but quickly helped to expedite things when I communicated the issue to her.

Another example of successful collaboration lies in the coordinated response to the catch-22 of the agency and IRB each calling for the other's approval first. The compromise of the IRB and the agency providing conditional letters of approval was built and facilitated by my professors and I. Once again, a solution was built through collaboration that allowed for the interests of each entity to be satisfied so that progress could continue.

Hopefully, Ron's collaboration with his professors and the IRB will yield a solution to his difficulties in gaining approval to invite participants for his study. In his case, it was important to build a compromise from information that the IRB was not aware of, such as the patterns of resistant behavior associated with the population he intends to study.



## VI. Conclusion

Successfully fulfilling the role of a principal investigator, especially for the first time, is much more difficult than it may seem. A principal investigator's tasks are collaborative ones that require him or her to be as clear as possible about his or her intentions and to understand the interests of each party involved so that compromises can be built as solutions to the inevitable barriers between the researcher and the gathering of data. When seeking to have direct contact with adult human research subjects, the IRB process can be both a blessing and a curse. While absolutely necessary and undeniably helpful to the researcher, the IRB works virtually single-mindedly in the interest of the participants in research. Again, this is positive and necessary as one easily learns from the notoriously harmful research studies of the no-too-distant past, but can prevent helpful research from being conducted if the principal investigator is not a shrewd and inventive enough collaborator. The principal investigator must adapt to their requirements and conduct research on their terms as much as possible.

The phrase 'day for night' is used in filmmaking to refer to technique in which special photography is used such that a sunny day appears to be a moonlight night. To shoot day for night, a director coordinates the resources, both human and technological, at his or her disposal to create the desired end result out of conditions in which achieving that result may seem impossible. Such innovation is an appropriate metaphor for beginning researchers, since a principal investigator must learn to collaborate with others so that the desired results are achieved regardless of the conditions under which they are sought.

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## Vita

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