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Naturalistic Observation in Public Settings: Applying for Institutional Review Board Approval

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Collaborative interaction with Institutional Review Boards (IRBs) is an essential component of the research process. While the social scientific community clearly recognizes the ethical obligation to protect human research participants from harm, we are often uninformed about the specific procedures and operations of IRB committees. The ethical issues relating to naturalistic observational methods have been particularly laden with ambiguity, serving as a perpetual "gray area." The present article provides an overview of federal guidelines regarding the ethics of naturalistic observation. The manner in which an IRB reviews a research proposal is described, emphasizing the perspective taken towards a study proposing naturalistic observation. Practical information regarding successful collaboration with IRBs is provided, using examples of studies that vary in their potential risks to volunteers.

Keywords: Naturalistic Observation, Ethology, Ethics, Institutional Review Board, Data Security, Privacy, Informed Consent, Minor Assent

Introduction

Observation of behavior in naturalistic settings is central to the discipline of ethology. Ethologists have traditionally focused on naturalistic rather than laboratory settings for studies of humans as well as other animals. At present, naturalistic observation is widely employed in anthropology and in psychological research with children. However, psychologists have increasingly turned to the use of self-report questionnaires and rely heavily on laboratory rather than field studies. Each method has a role, depending upon the specific research question. Naturalistic observation still has a useful function in understanding humans, particularly with dimensions of behavior that are not conscious, where self-reports are not reliable, or where nonverbal behavior itself is the topic of study (Eibl-Eibesfeldt, 1989; Freedman, 1979).

Anthropology has a long-standing tradition of participant observation. Structured time-sampling methods are employed to obtain objective measures of behaviors of interest. For example, Barry Hewlett's study of paternal behavior among the Aka Pygmies used observation of fathers and infants (Hewlett, 1991). Families with infants were followed for 12 hours per day, and an observer measured caretaker-infant interactions. Using detailed observations of activities while holding an infant (i.e., play, transport, affection, soothe, clean, and feeding), Hewlett compared the amount of direct paternal care provided by men with their level of kin and material resources (e.g., number of brothers and size of hunting net owned). The correlation between resources and direct care was negative. Would a significant correlation be found using subjective rather than objective methods? Self-report questionnaires or personal interviews are subject to bias when researchers

inquire about personal topics, which include economic resources and parenting practices.

There is also a long history of studying children using observational methods, both in public playgrounds and in laboratory settings (Blurton Jones, 1972; McGrew, 1972). Children cannot fill out surveys until reading and writing skills are developed, and their level of introspection and self-awareness is usually not sufficient for studying their motivations and abilities. A recent example is a study applying observational methods to understand how children use libraries (McKechnie, 2000). McKechnie (2000) placed a recording device in a sweatshirt which was worn by four-year-old girls during a visit to the library, and compared this data with field notes gathered during the visit as well as diaries filled out by the children's mothers. Although no specific a priori hypotheses were made in this ethnographic study, McKechnie generated positive overarching themes regarding how young children react to being observed in research: namely, the children were highly cooperative with the researcher, were aware of what "research" is, and acted "natural" while being tape-recorded, according to their mother's reports.

Scientists generally consider these types of studies to be ethical in the usual sense of the word, but one must also ensure that they fit criteria used by an ethics review board. The two examples mentioned above involve naturalistic observation with the consent of participants. Until recently, naturalistic observation in public settings was not regulated by governmental policies, and researchers followed the ethical codes of their professional societies, the American Anthropological Association (AAA, 2004) or the American Psychological Association (APA, 2010). Though the AAA lacks a specific policy regarding naturalistic observation without participant's awareness or consent, the code clearly states that the kind of informed consent necessary will depend upon the nature of research being conducted. Further, no research participant may ever be placed in harm's way during any type of study. The APA states that informed consent may be dispensed with if confidentiality is protected and the research being conducted is:

> "…only anonymous questionnaires, naturalistic observations, or archival research for which disclosure of responses would not place participants at risk of criminal or civil liability…" (APA, 2010; Standard 8.05).

Guidelines were put in place by the United States (US) government in 1974 (45 Code of Federal Regulations 46) after abuses in the biomedical arena, such as the Tuskegee syphilis study (Jones, 1981). The Belmont Commission developed the basic policies in use today (The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978). Research studies in general must show 1) respect for persons, which requires that we not use them for research without their informed consent; 2) beneficence, which requires that the benefits of research exceed the potential risks; and 3) justice, which requires that the burdens and benefits of research be fairly distributed. These tenets have been codified in federal regulations of the US government and similarly in other countries. The interpretation of these guidelines by ethics review boards is very structured, and research studies are evaluated using specific criteria. This article will describe guidelines related to observational research and how ethics review boards generally conduct reviews. To illustrate, four example studies will be presented, which vary in risk level and ethical issues.

Ethics of Observational Research

In the US, research with human subjects is usually reviewed by an institutional review board (IRB), and IRB review is required for all federally funded research. An IRB consists of at least five members, including scientists as well as a nonscientist and a member from the community. The guidelines are available in the federal register (Department of Health and Human Services, 2009a) and are overseen by the federal Office of Human Research Protections (OHRP). Most universities follow these guidelines ("the Common Rule") fairly closely, although some adopt stricter policies. It is likely that US guidelines will be revised in the near future; the OHRP has begun the process for a revision (see below for details). The timeline for implementation is currently unclear; therefore, the information in this article reflects the existing

regulations, but we note potential future changes that are relevant.

According to federal guidelines, observation of nonidentified persons in a public setting is not defined as human subjects research, and hence is not within the purview of the IRB. However, some universities require that all research be reviewed, if it is conducted by its faculty or students or on its premises. If there is any doubt, researchers should err on the side of caution and submit an application.

Whether research involving human subjects is covered by federal guidelines hinges upon the distinction between public and private settings, whether the participants being observed are individually identifiable, and whether the investigator has any interaction with the participants. Thus, IRB approval is needed if any identifiable private information is collected or if researchers interact with participants. The guidelines consider as *private* any information "about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record)" (45 CFR 46.102[f]; Department of Health and Human Services, 2009b). Studies that qualify as "human subjects" research must be approved by the researcher's institution. The type of review depends upon the level of risk to research volunteers.

Many psychosocial studies fall into a category of human subjects research that is "exempt" from IRB review. However, one's institution determines exemptions; researchers may not exempt themselves. In many universities, the IRB makes the exemption decision. The term "exempt" is misleading; human subjects research may be exempt from review by the IRB, but it is not exempt from institutional approval at some level. There are six categories of research that are eligible for exemption, including educational research, anonymous surveys, and studies with existing archival data (45 CFR 46.101[b]; Department of Health and Human Services, 2009c). Exemption category 2 covers naturalistic observation:

> 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
>
> (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subject; and
>
> (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Applications to an IRB will be handled in two main ways, expedited or full-board, depending upon the level of risk of the research. Most research that has minimal risk (defined as the risks encountered in everyday life or during routine clinical procedures or tests) can be reviewed in the expedited pathway, that is, by the committee chair or designated reviewer rather than the full committee. Projects with more than minimal risk are reviewed by the full board. Biomedical research studies are more likely to present higher risk to participants, but psychological studies can have risk of emotional distress or threats to confidentiality of private information. There are seven categories of research that are eligible for expedited review, along with two other categories that are eligible for expedited renewal after initial approval (45 CFR 46.110). Most ethological research would have minimal risk, and because of a focus on behavior, would fit category seven for expedited review (45 CFR 46.110; Department of Health and Human Services, 2009d):

> Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

International Ethics Considerations

The OHRP has compiled a document delineating the ethical requirements for human subjects research in most nations around the world (OHRP, 2011). A cursory perusal of this document reveals that countries vary greatly in their ethical expectations and level of oversight. Further, it is obvious that the extent of restrictions set for social science research pales in

comparison to the restrictions set for biomedical research studies (such as those involving drug testing, medical devices, and use of human tissues).

In some nations, in fact, there is virtually no official oversight of human subject research in the social sciences. Germany's ethics policies are restricted to biomedical research only, although social science researchers must abide by European regulations that include the protection of individual privacy. The nation is reported to be considering adopting more stringent official guidelines (German Data Forum, 2010). The situation is similar in Denmark, with all social science research being exempt from governmental ethics scrutiny (Holm, 2006). In the Netherlands, research requires oversight only if participants are "subjected to procedures" or required to follow "rules of behavior," which effectively exempts all types of nonintrusive ethological observation (Central Committee on Research, 2011). Finland explicitly states that observing subjects in a public place does not require ethical review (National Advisory Board on Research Ethics in Finland, 2011), while Sweden requires review only of research aimed at affecting the subject either physically or psychologically, a definition that would not include naturalistic observation (Eriksson, 2011).

The European Commission's Seventh Framework Programme for Research (FP_7) requires ethics review prior to funding applications (European Commission Community Research and Development Information Service, 2011). Guidelines recommend, though do not legally require, that covert observational research should be done only when it is the sole effective and feasible method, and when there is no risk of harm or suffering to those being observed. This organization also acknowledges the infeasibility of obtaining prior informed consent in these types of research studies.

How IRBs Evaluate Research Studies

When evaluating a research study, ethics committees compare the potential risks to human participants to the potential benefits from knowledge generated by the study. The risks to human subjects of ethological observation are usually minimal: risks to confidentiality and privacy. Nevertheless, in their IRB applications, investigators need to delineate the benefits that will be derived from the research. The scientific benefit of a particular study may not be clear to scientists from other disciplines, to nonscientists, and to community members. Federal regulations define the level of risk to participants in relation to the risks encountered in everyday life. The IRB will consider the risks and how they are mitigated. The level of risk determines whether a project is reviewed by the full committee or whether it can be expedited. Decisions about the type of review are shown in flowcharts by the federal Office of Human Research Protections (Office for Human Research Protections, 2004). As stated earlier, studies where risk is greater than "minimal" are reviewed by the full committee. Expedited applications are reviewed by the committee chair or other designated reviewer, and hence they typically are completed more quickly. The IRB reviews how researchers recruit volunteers and how their consent to participate is obtained. Typically, volunteers are fully informed about study procedures and given an opportunity to ask questions. The committee will also scrutinize any incentives offered to subjects for their participation. The following sections give more detail about risk, confidentiality of research information, and informed consent.

Evaluation of Risk Level

With naturalistic observation, in contrast to biomedical experiments, risk takes the form of psychological discomfort or invasion of privacy. Psychological discomfort might include a participant's embarrassment, shame, depression, anxiety, or other negative affect. IRBs expect that potential research participants will be informed that surveys include questions that might be disturbing. Such a statement is typically included in the consent form. If people are warned before agreeing to participate, they are less likely to be upset afterwards. The consent form should also state that volunteers may refuse to answer a question if they so choose. It is a participant's right to skip questions, despite the havoc it wreaks on the statistician dealing with missing data during analysis. A detailed consideration of the types of potential harm in social/behavioral studies, and ameliorative

measures, may be found in Table A of the "Risk and Harm" report prepared by the Social and Behavioral Sciences Working Group on Human Research Protections (2004). It is also possible for social, economic, or legal harm to occur. Surveys that contain questions about any illegal or stigmatized activities move the potential risk beyond the minimal level. Where such information is gathered, and a participant's identity is revealed in the written informed consent document, a minimal risk level can be attained by waiving documentation of consent (see "Informed Consent" below).

The collection of personal information for research may entail a risk to confidentiality, which we will call "disclosure risk." This risk exists when information could be damaging to an individual if revealed, for instance behavior related to the use of illegal drugs. Behavior in public settings may or may not be subject to disclosure risk. Socially unacceptable activities may be observed by researchers, such as alcohol-influenced behavior in bars. Cultural variation should be considered in determining the level of risk for research conducted outside the US, where laws and norms may be different. If information has disclosure risk, IRB review is expected, and the project will not be considered exempt. Information collected by observation of public behavior (and also through surveys or interviews) has disclosure risk where "disclosing participants' responses outside the research context could reasonably put the individuals at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation" (45 CFR 46.101[b]; Department of Health and Human Services, 2009d). The Centers for Disease Control refers to such data as "sensitive" (Centers for Disease Control and Prevention, 2012). Expedited review can be used in these cases, if provisions are in place to protect confidential information from inadvertent disclosure.

Researchers use various practices to protect confidentiality. Research data that contains unique identifiers for individuals should be protected by using numerical codes rather than names on records. Paper records should be stored in locked cabinets, and electronic files should be password-protected. If research information has disclosure risk, these files should be encrypted. Only aggregated data should be published, with data aggregated over groups of sufficient size to prevent inadvertent identification (usually at least five cases). Further, access to data should be limited to the research team. However, it is difficult completely to protect electronic information that is stored on a network. Serious confidentiality concerns warrant storing information on a desktop that is not connected to the internet. Where illegal activities are the topic of study, the federal government can issue a Certificate of Confidentiality (COC) as protection from a potential subpoena (Centers for Disease Control and Prevention, 2012). It should be noted, however, that there is at least one case where a COC did not prevent release of research records in a legal proceeding (Beskow, Dame & Costello, 2008).

Individuals can be identified in photographs, videotapes, or audio recordings. Nevertheless, observational research with adults still qualifies as exempt if the behavior being recorded is not damaging (i.e., with disclosure risk). Recorded observations of children may be exempt if the researcher does not interact with the participants (Department of Health and Human Services, 2009c). Videotapes may not be disseminated beyond the research setting unless sequences are made anonymous by the masking or pixilation of faces. Researchers are responsible for obtaining the technology to protect an archive from unauthorized publication.

The European Commission and various states within it have stringent codes protecting private data (Korff, 2010). In the US, guidelines for research data security will probably be revised in the near future; the US government is considering changes to policies governing research ethics. A central component consists of tightening standards for data security. In essence the US government is proposing to apply the same standard to identifiable research data as are applied to health records by the Health Insurance Portability and Accountability Act of 1996 (HIPAA; Department of Health and Human Services, 2003). The expectation would be that research data will be de-identified before storage in any research archive, file, or data set. HIPAA

guidelines define unique identifiers for individuals. This information must be excluded from research files unless consent or a waiver of consent has been granted. These identifiers include the obvious name, address, phone number, driver's license number, and medical case number, but also birthdate and age, if the individual is older than 89. The European Commission is also extensively researching the data security issues related to identifiable research data (Korff, 2010).

Informed Consent

A central tenet of ethical research is voluntary participation, i.e., informed consent. This principle applies unless the study involves only observation of behavior in public. For any other research, ethical practice requires obtaining consent. Investigators cannot expect that consent requirements would be waived (but see deception section below). It is considered disrespectful of persons to use them in research without consent.

Waiver of *written documentation* of informed consent is possible under certain conditions, where only oral consent is obtained. Individuals who are unable to read or write may give oral consent, documented by a witness who is not the researcher. Where participants speak a different language than the investigator, the consent form must be translated into their language. In some cases, a short-form written version may be combined with oral presentation of the full elements of informed consent where a witness fluent in both languages is present. Waiver of documentation is routinely approved for electronic surveys conducted through the internet. The relevant section of the Common Rule states that written documentation of consent may be waived by the IRB if it finds either of two conditions (Department of Health and Human Services, 2009e):

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Anthropologists may find the written consent requirement unnecessarily stringent, given their research in other cultures, and the federal guidelines may seem incongruous in this context. Ethnographical participant observation does fit the criteria for waiver of documentation, in that the research has minimal risk and there are no procedures that would otherwise require consent outside of the research context. Obviously, anthropologists talk to their subjects at length and discuss their purpose in observing them. Bosk and De Vries (2004) assert that ethnographers "cannot inform our subjects of the risks and benefits of cooperating with us… we cannot specify risks because we do not know what we will find, what interpretive frameworks we will develop for reporting what we do observe, and who the world around us will change to make those findings seem more or less significant" (p. 253). Nevertheless, an attempt to explain the risks and benefits must be made to the IRB.

Research with Children

Current guidelines require the permission of a parent or legal guardian for a child's participation in research, but also expect the child to indicate willingness by giving assent (CFR Subpart D, 46.40. For full details, see the guidance provided by OHRP [Department of Health and Human Services, 2009f]). By giving assent, a child indicates voluntary participation, free of coercion by parents. Regulations differ depending on the risk level of the research and its potential to benefit a child directly, as might be the case with an experimental medication. Assuming that ethological research will be minimal risk, child assent and one parent's written consent is required. In the US, children are defined as any minor under age 18. Assent is typically expected for minors aged seven to seventeen. Commonly, children under age seven are not expected to assent; the parent's consent alone suffices. Many universities will expect signed *assent* documents, which are very brief, simplified summaries of the adult informed consent. Further, it is frequently expected that these written forms will use very simple language, written for third-grade level for children aged seven to twelve, while adolescents will be given forms that are written at a fifth-

grade reading level. Universities vary in whether children aged seven to twelve are expected to sign an assent document or simply to assent orally.

With their parent's consent, children have been observed covertly. Pepler and Craig (1995) studied patterns of aggression in children on a school playground using video cameras and remote microphones; this study is distinctive in that parents were informed of the methodology and gave informed consent, but the children were not informed and did not give assent. Pepler and Craig (1995) acknowledged issues of the children's confidentiality and privacy, as well as ethical issues such as what to do when a child whose parent has not consented enters the camera field. (All parents in this study consented.) They defended covert observation with the argument that investigation of bullying and aggressive behaviors requires that children's behavior be unconstrained, meaning that they cannot know they are being watched. Waiver of assent on the part of the children may be appropriate in this circumstance in that research will ultimately lead to more effective intervention strategies to prevent bullying.

Deception in Research

In cases where the success of a research study depends on deception about the purpose or rationale of study, such deception may be approved, if justified. Some IRBs do not allow any deception, based on respect for persons. Others may allow omission of the study hypothesis as long as the purpose and procedures are described accurately. Deception about study procedures is rarely approved, but may be considered essential for a research design. In such cases, debriefing subjects after completion of the study is expected. At that point subjects should reaffirm consent for use of their data. An IRB may approve deception in a research protocol in instances where this is the only feasible method to investigate the effects in question, as in the well-known Cohen et al. (1996) study examining the effects of the Southern US culture of honor. In this study, a research confederate bumped into unsuspecting college students in a hallway and called them a derogatory name, after which the physiological and cognitive stress levels of students were measured. Had participants been informed beforehand of the true nature of the experiment, it would have altered their reactions. It is more important to note, however, that during their thorough debriefing, these participants reported low levels of anger or upset regarding the deception, along with high levels of positive emotion regarding participation (Cohen et al., 1996). Debriefing is the most critical aspect of studies involving deception, and it played a prominent role in Burger's (Burger, 2007) replication of the Milgram shock experiments (Milgram, 1963). In addition to modifications such as stopping at a lower level of punishment (fake 150-volt shocks) and screening out candidates with potential emotional problems, Burger differed from Milgram by immediately informing participants after completion of the experiment that no real shocks had been administered.

Ethological Studies with Increasing Levels of Risk: IRB Review

To illustrate how potential risk increases depending on the design of a particular research study, we present below synopses of four fictitious research studies—none have been submitted for IRB review (to our knowledge). The studies are presented here in increasing order of risk. Our hypothetical social scientist brings an evolutionary perspective to his research on parental behavior. Because parents are rarely objective or accurate in their assessments of their attitudes and behavior towards their children, the researcher chooses to observe parents interacting with their children in public playgrounds, rather than just having them fill out self-report questionnaires. There are several ways to design such a study, and the ethics review will differ accordingly. In Study #1, no IRB review is necessary, because it does not fit the federal definition of Human Subjects Research. Study #2 is an example of a research project that is exempt from IRB review; Study #3 is one that warrants an expedited review; and the final example, Study #4, requires full board review.

No Review Required

In this study, parents will be observed at a distance by the researcher. The parents are presumed adults. Participants will not be identified. Observations will be conducted in real time, without recording devices. Behaviors to be coded will include all actions by the parent directed at the child, including speaking, playing, discipline, physical guiding, watching, and actions not directed at the child (conversing with others, sitting); distance from the child will also be recorded. Given that the observations take place in a public setting, with no intervention or interaction with the investigator, federal guidelines would not consider this study to be human subjects research (OHRP, 2004). The purpose of the research is to develop generalizable knowledge, but the definition of human subjects is not met. Exhibit 1 shows an example letter the investigator could write to the IRB chair or designated institutional official, requesting a determination about the study.

Exhibit 1. *Letter to IRB Chair Verifying that a Study Does Not Need IRB Review*

Dear IRB Chair:

I propose to conduct a study of parental interactions with children. The participants are adults, observed in the public playgrounds in several neighborhoods. Behaviors will be recorded and timed by stopwatch. Behaviors include all actions by the parent directed at the child, including speaking, playing, discipline, physical guiding, watching, and actions not directed at the child (conversing with others, sitting); distance from the child will also be recorded. A research plan is attached, which explains the rationale and methods. From reading the university's guidelines, it appears that this project would not be considered to be human-subjects research. The observations take place in a public setting. No intervention or interaction by the investigator will occur. Participants will not be identified. Please confirm that no IRB review is necessary for this study.

Sincerely,

Professor Budding Ethologist, Jr.

Exempt Designation

The next example does qualify as Human Subjects Research, but this study fits the "Exempt" criteria. Exhibit 2 shows a letter the investigator could write to the IRB Chair or designated institutional official, requesting this determination. The setting is the same, but now the researcher proposes to gather demographic data by approaching the adults with a questionnaire to complete. Thus, it differs from the first in that it involves interaction with the participants by the investigator. The items queried are: parent's age, gender, education, marital status, number of children and their genders, relationship to child at the playground, and child's age. No identifying information will be requested on the survey. The project fits Exempt criteria. The specific guidelines are 45 CFR 46.401(b)(2), category 2: research involves only the use of educational tests, survey procedures, interview procedures, or observation of public behavior. Participants are not identified and no private information is collected. This exempt category applies to observational research with children in public setting only "when the investigators do not participate in the activities being observed" (45 CFR 46.401[b];Department of Health and Human Services, 2009c). If the US revised guidelines that are under consideration are implemented, this study will require only that a registration form be completed and filed. No formal review or determination would be needed.

Exhibit 2. *Letter to IRB Chair Requesting Exempt Designation.*

Dear IRB Chair:

I propose to conduct a study of parental interactions with children. The participants are adults, observed in the public playgrounds in several neighborhoods. Behaviors will be recorded and timed by stopwatch. Behaviors include all actions by the parent directed at the child, including speaking, playing, discipline, physical guiding, watching, and actions not directed at the child (conversing with others, sitting); distance from the child will also be recorded. In addition, I will approach the adult and request that he or she complete a brief demographic questionnaire. The items queried are: age, gender, education, marital status, number of children, their genders, relationship to child at the playground, and child's age. No identifying information will be requested on the survey. A research plan is attached, which explains the rationale and methods. From reading the university's guidelines, it appears that this project fits "exempt" criteria. The specific guidelines are 45 CFR 46.401(b)(2), category 2: research involves only the use of educational tests, survey procedures, interview procedures, or observation of public behavior. Participants are not identified and no private information is collected. The investigator will not participate in the activities being observed.

Sincerely,

Professor Budding Ethologist, Jr.

Expedited Application

The next study does require review by the IRB, but it qualifies for the Expedited process, rather than requiring review by the full board. The researcher wishes to videotape the parental interactions at the playground, and the questionnaire has been expanded to include more questions, such as income. The scientific rationale for such a study could be to relate types of interactions to level of resources available for a parent, or simply to determine how interactions vary by age and whether a parent has other children. A scientific argument can be made that parental investment may vary by age and number of other children. Interactions might vary by relationship to the target child, for example between step- and biological parents. Adults will be informed of the videotaping and asked for written consent. Because the videotaping will include the children themselves, the assent of the child must also be obtained. As described above, children aged seven to seventeen are expected to give assent, documented by a separate form, and their parent/guardian signs the legal consent for the child's research participation. Regardless of the potential high refusal rate for participation in this study, it could add to our knowledge about parent-child interactions beyond what can be gained in a laboratory format. If a waiver of consent documentation is requested, the rationale must be described so that the IRB can determine adherence to specific federal guidelines.

IRB applications always have a highly structured format, so that all important information is very clear for reviewers. Many institutions now have an online submission system. Questions on the form are geared to determine risk level, mitigation of risk, confidentiality protections, whether any vulnerable groups are included, and so forth. As part of the application, an Informed Consent form must be included. Institutions typically provide templates and examples on the IRB website. Generally, a written proposal must be included, which allows the IRB to evaluate the benefit of the study. Readers are referred to the resources at their own institutions for further details. All survey or interview questions must be included in the application, to enable the IRB to determine whether information with disclosure risk will be collected. Exhibit 3 provides an outline of a typical IRB application for a minimal-risk, expedited study.

Exhibit 3. *Typical Contents of an IRB Application for a Minimal Risk Study*

Objectives: The purpose of this study is to understand parents' interactions with children. Researchers wish to observe parents and children at the public playgrounds in several neighborhoods.

Synopsis of Research Plan: An abstract of the study in nontechnical language. Attach a research proposal.

Procedures: Researchers wish to observe parents and children at the public playgrounds in several neighborhoods. Interactions will be videotaped for detailed coding and timing of behaviors. Behaviors to be coded include all actions by the parent directed at the child, including speaking, playing, discipline, physical guiding, watching, and actions not directed at the child (conversing with others, sitting); distance from the child will also be recorded. In addition, parents will be asked to complete a brief questionnaire. The items queried are: age, gender, education, income (personal and family), marital status, number of children, their genders, relationship to child at the playground, and child's age. A copy of the survey is attached.

Recruitment and consent procedures: As people arrive at the playground, I will approach them and explain the study and videotaping. Written consent and assent forms will be used (attached). The recruitment goal is 30 parent-child pairs, with parents over age 18. Parents of either sex will be included. Children will be any age under 12 (or other age selected by investigator).

Description of possible benefits and possible risks to volunteers: The study will not benefit individual volunteers, but the findings will add to our scientific understanding of parent-child interactions. While much information about parenting has been obtained using self-report questionnaires and laboratory studies, behavior in a naturalistic setting may differ. Possible risks are minimal. There is a potential that volunteers might feel embarrassment and self-consciousness when being observed and videotaped. They might feel inconvenienced by interactions with the investigator and by taking time to complete the questionnaire. They may feel worried about whether their behavior will be judged or criticized by the investigator, particularly if they think of the investigator as a psychologist. Because videotaping introduces the risk of breach of confidentiality, there is a risk that images could be broadcast outside the research context. In addition, observers may witness physical abuse toward a child. In such cases, mandatory reporting requirements will be followed. This possibility is described in the consent form.

Mitigation of risks: Volunteers will be fully informed of possible risks and benefits prior to any observation or videotaping (see Informed Consent and Minor Assent attached). Confidentiality and privacy of questionnaire responses, data, and videotapes will be protected, within

legal limits. Data will be stored with code numbers only, without any identifying fields. A code number will link the video with the questionnaire and the real-time observations. Videotapes will be stored on password-protected media files in a locked cabinet. Only members of the research team will view the files, and any students involved will sign a special confidentiality pledge. Computers used to work with these videotapes will not have an internet connection. After detailed coding of the videos is completed, and data are statistically analyzed, videos will be destroyed.

Full Board Application

The next study entails greater than minimal risk, thus requiring full board review. In addition to videotaping and a survey requesting private information, this new version introduces a staged situation to elicit parental protective behavior. As mentioned above, a scientific argument can be made that parental investment may vary by age and number of children. From an evolutionary perspective, a mother's impulse to intervene physically to protect a child would be expected to be greater, for example, for an older woman with no other children than for a younger one with several children (all else being equal).

An intervention will be staged, in order to assess the degree of protectiveness shown by an adult to the child. At a point in the videotaping session, a male research confederate will approach the child and speak to him or her. The confederate will be dressed in a disheveled manner and have an offensive odor. Behavior codes for protective behavior will be included in the measures coded on the videotapes. An example is a parent physically moving to stand between the man and the child. The parent's saying something to the confederate, such as, "get away" is another example. Whether this study requires full-board review rather than expedited review depends upon whether it incurs more than minimal risk, meaning that it exceeds the dangers encountered in everyday life. In reality, the appearance of a disheveled stranger at a public park is certainly within the realm of everyday possibility. However, the confederate's speaking to the child would probably be considered to exceed minimal risk. Full-board review would also be likely because of the use of deception about the confederate.

The potential risks of the study are emotional or psychological ones. As in the previous study (Exhibit 3), participants may feel embarrassment and worry. In addition, they may feel fear and anger when the confederate approaches their child. There is a remote possibility of physical injury if a participant experienced a physical reaction such as a cardiovascular event as a result of stress, or if a participant tripped and fell while trying to intervene between a child and the confederate. Additionally, the child may feel emotional distress when approached by a stranger.

In order for such a study to receive IRB approval, the scientific benefit must exceed these risks. The investigator will have to write a convincing rationale for the research proposal. He or she will need to justify the use of deception, and explain why the study must be conducted using the confederate. Evidence that self-reports about the relative extent of parental protective behavior are not accurate should be presented. When deception is employed, debriefing afterwards about the study's true purpose is expected, and at that point, participants must be given the choice of withdrawing from the study. Videotapes may not be used without the participant's reconsent after debriefing. Volunteers have the right to withdraw from a research study at any time. The informed consent document might state that participants will be videotaped, and the investigators may stage an event, such as bringing in another child. This description allows the participants to give consent to the procedures of the study without knowing the full scientific purpose. Potential for psychological harm can be ameliorated by initial consent along with sensitive debriefing (Social and Behavioral Sciences Working Group on Human Research Protections, 2004). .

For this study, education of the IRB might be necessary, as done by Jerry Burger (Burger, 2007) in his proposal to replicate Milgram's (1963) obedience studies. He asked an expert to write an evaluation of the ethical issues. In addition, Burger mitigated potential emotional risks to research participants by having all potential volunteers screened by a clinical psychologist to detect any fragile individuals who might be unduly stressed by the experience. The playground study proposed here does not seem

to require this screening, but a contingency plan is in order, for example, in the event of accidental injury to a participant during the observations.

Exhibit 4. *IRB Application for Research with More than Minimal Risk*

Objectives: The purpose of this study is to understand parent's interactions with children, especially their willingness to protect them from strangers. Researchers plan to observe parents and children at the public playgrounds in several neighborhoods. An intervention will be staged, in order to assess the degree of protective behavior shown by an adult to the child.

Procedures: Same as above (Exhibit 3) with the addition that at a point in the videotaping session, a male research confederate will approach the child and speak to him or her for several minutes or until the parent/adult asks him to leave. The confederate will be dressed in a disheveled manner and have an offensive odor. Behavior codes for protection will be included in the measures coded on the videotapes. An example is a parent physically moving to stand between the man and the child. The parent's saying something to the confederate, such as, "get away" is another example. The confederate will be a trained actor, and the several minute dialog will follow the same script each time (text is attached).

Recruitment and consent procedures: As people arrive at the playground, I will approach them and explain the study and videotaping. Written consent and assent forms will be used (attached). The consent and assent forms state that the investigators may stage an event, such as bringing in another child. The recruitment goal is 30 parent-child pairs, with parents over age 18. Parents of either sex will be included, with children of any age. After the confederate encounter, the observations will be ended and participants will be debriefed about the true purpose of the study. At this point, they will be asked to review the consent/assent form and confirm their willingness to participate in the study.

Description of possible benefits and possible risks to volunteers: Same as above, with the addition that volunteers might feel fear or anger during a staged event, and might feel worry because they do not know the full scientific purpose of the research study.

Mitigation of risks: Same as above, with the specification that volunteers will be informed of possible risks and benefits prior to the study session (see Informed Consent and Minor Assent attached), but they will not know the full purpose of the study, and they will be deceived about the exact nature of the staged event. They will, however, consent to the possibility of a staged event occurring. Debriefing after the study session will focus on explaining the rationale for deception, assessing any lingering emotional distress, and addressing any concerns of participants. Confidentiality measures will be reiterated. A text of the debriefing script is attached.

These four ethological research studies illustrated increased risk by including identifiable private information, videotaping, deception, and a staged intervention. They all were focused on parental behavior, with the last attempting to describe parental protectiveness. The first did not require IRB review, because it did not fit the federal definition of Human Subjects Research. The next fit that definition because participants could be identified, but it qualified for exempt designation. The next two studies required review. The studies are not perfect, by any means, but they meet ethical standards of the US government and the American Psychological Association and the American Anthropological Association. An investigator who submitted a thorough and credible application to their IRB that explained the issues sufficiently could reasonably expect the application to be approved.

Conclusion

The thought of being reviewed by an Institutional Review Board strikes fear in the hearts of many researchers, who assume that the IRB will obstruct their research programs. But with planning—both in research design and in the way it is described in the IRB application—this does not have to be the case. The mission of IRBs is not to obstruct research, but to evaluate projects using highly structured federal guidelines. Researchers who can communicate about their studies within this framework will have a much easier time of it.

Bosk and De Vries (2004) have provided a comprehensive summary of the conflicts of interest between IRBs and social scientists conducting ethnographic and other forms of observational research. The general conclusion was that, given that IRB oversight will not be eliminated, it is in the best interest of social scientists to become more familiar with IRB expectations and to work in a collegial manner to improve upon the system, making it more suitable for a social scientific rather than a strictly medical research model. Bosk and DeVries (2004) recommended an objective study of how IRBs work, a topic for which there is currently a paucity of research in the social scientific literature.

A primary problem in the relationship between social scientific researchers and IRB committees

is inadequate understanding of what the other is doing (Bosk & De Vries, 2004). Ethnographic and ethological researchers may become defensive when asked to delineate how they will manage a number of ethical expectations that they believe are not pertinent to their methodology in the manner laid out by traditional IRB requirements, such as how to obtain informed consent, how to predict risk or harm (which is assumed to be minimal in these types of studies), and how research data will be analyzed and hypotheses tested. Therefore, Bosk and DeVries (2004) recommended that social scientists, rather than becoming defensive or evasive, provide a clear explanation as to how they intend to conduct every aspect of their research, as well as explaining in clear and simple terms how and why their research differs from expectations posed by a medical model. It is further recommended that IRB committees bring in more members from the social sciences, particularly those who are familiar with qualitative research, naturalistic observation, and ethnography.

IRBs should be able to review and approve studies where the importance of the research question is clear and where the rights of participants are clearly respected. Bosk and De Vries (2004) urge social scientists to serve as members of IRB committees. Qualitative researchers would be especially valuable additions to committees, because this method does not fit the traditional expectations for social or biomedical science. Researchers may need to explain more of the theoretical and methodological foundations of their study than would be necessary to put forth in a typical rationale for their scientific peers.

In the future, ethological research may have fewer requirements for institutional review. As mentioned above, the US OHRP is considering revising the guidelines for social/behavioral research. They are reviewing public comments solicited by an advance notice ("Notice of Proposed Rulemaking" [Department of Health and Human Services, 2011]). Several issues described in the document are especially pertinent for observational research (Issues 14-17).

One potential change with widespread implications is that OHRP may set uniform standards to assure privacy and confidentiality protections to subjects. All studies would be subject to new data security protections (Issue 14). With these protections in place, some projects will not need review. However, universities could still adopt stricter policies that require all research to be reviewed. If the new guidelines are implemented, criteria for exemption will be clarified (Issue 15). Currently, administrative review by one's home institution is usually done to determine that a study is exempt. Instead, under the proposed rules (Issue 16), researchers would file a brief "registration" form with their institution or IRB, after which the study could begin. Periodic audits of studies would be done to ensure compliance with regulations. Some survey and observational studies that were not previously exempt may qualify in the future, because of the new data security precautions. With secure data, risks to privacy and confidentiality become less relevant (Issue 17). Public comments that were submitted by October, 2011 will be incorporated into a final draft of new rules, and another public comment period will be opened. Readers are encouraged respond to OHRP with their opinions.

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