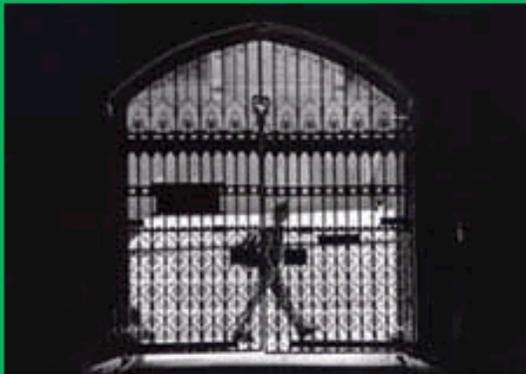


TEACHERS COLLEGE

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**AVOIDING HUMAN
SUBJECT PROTECTION
PITFALLS
IN THE SOCIAL AND
BEHAVIORAL
SCIENCES**



A Guide for First Time Applicants for Institutional Review Board (IRB) Review

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Avoiding Human Subjects Protections Pitfalls in the Social and Behavioral Sciences

The Teachers College Institutional Review Board (IRB) is a committee composed primarily of faculty with representation from each academic department, which reviews all faculty, staff and student research involving human subjects for adherence to ethical standards. Please note that all doctoral students must obtain a letter of IRB approval before being certified as a doctoral candidate. The Office of Sponsored Programs (OSP) provides support for this committee with staff in the IRB office at 422k Thompson Hall.

Potential risks to subjects in the social and behavioral sciences tend to cluster around issues of confidentiality. Below you will find excerpts from actual applications submitted to the TC IRB over the last three years. Each represents a problem that arises fairly frequently and that reviewers request more or less the same revisions each time they come up. Several complete IRB applications representative of various methodologies and levels of risk are presented at the end of this guide for additional reference.

OSP and the Teachers College IRB hope this guide will save on a significant amount of back and forth between investigators and reviewers. However, we urge investigators to keep the following in mind:

- Small differences in methodology, the research question and subject population might render some of the suggested procedures inappropriate or irrelevant in your own protocol. One area where that illustrates this point vividly is research involving populations with some type of cognitive or physical disability or a mental illness. Appropriate procedures can vary greatly depending on the nature and severity of the impairment, whether or not an individual is receiving medication to regulate symptoms, etc. Keep in mind that one of the central principles of human subjects protections is respect for persons and their ability to provide informed consent to participate in research. It's a mistake to make assumptions about a given individual's ability to give that consent based on their membership in a specific class of research subjects.
- There are times when a specific protection measure may skew research results or deplete the subject pool. Reviewers are sensitive to this possibility and try to make suggestions for revisions that balance the needs of subjects with the integrity of the research. You are not obligated to adopt any of the procedures described below if you feel they may have an adverse affect on research outcomes or participation. Remember that it isn't simply the presence or absence of risk that guides IRB decisions, but rather the ratio of risks to benefits. If you can demonstrate to reviewers that more stringent protections will have an adverse effect on your research and that the benefits of conducting the research without those protections clearly outweigh any additional potential risk, the IRB will consider your evidence and make its recommendations accordingly.

1. Pitfalls related to the Risk/Benefit Assessment

The risk/benefit analysis is the foundation of any IRB review. The Belmont Report, the basic statement of principles that serves as the basis for all federal human subjects regulations, states that ". . . a risk/benefit assessment needs to be conducted for all research. This assessment requires a careful array of relevant data, including, in some cases, alternative ways of obtaining the benefits sought in the research." Often, however, the risk/benefit section of the TC IRB application is the least developed

and least thought out. It is impossible for the IRB to assess whether or not the proposed protections are adequate if they aren't detailed completely. Researchers also tend to dismiss or minimize the possibility of their own actions causing harm to subjects. No researcher *intends* to harm subjects, but the fact that most harm occurs *unintentionally* renders intentions beside the point. A research design that acknowledges and takes steps to minimize these potential harms can demonstrate your scrupulousness to potential subjects and thus aid in recruitment. Here are some examples of common errors in the risk/benefit analysis along with how they were resolved.

1.1 Overstated Benefits in Consent Document

"Benefits are overstated" is perhaps the most frequent comment applicants receive from the IRB. Most of the time this error stems from an assumption that the research will work out as planned and the efficacy of the intervention will be proven. If the research project sets out to demonstrate the efficacy of an untried intervention or to prove a correlation of some sort, investigators cannot guarantee with absolute certainty that the benefits will indeed accrue to participants. Most of the time this problem can be resolved by recasting the sentences in the hypothetical, as in the following example:

Examining Models of Second Language Knowledge with Specific Reference to Relative Clauses A Model Comparison Approach, Doctoral Student PI.

Original: Risks and Benefits: Specifically, the results of **this study will provide educators with information** about how well learners at different stages of language development know about the form, meaning and use of relative clauses in expressions in English.

Revised: These results **could provide** them with information about how well language learners know about form, meaning and use of relative clauses in expressions in English.

It is usually best to avoid vague, "warm and fuzzy" benefits such as increased self-understanding or the knowledge that the subject has helped further the cause of science. Focus instead on concrete benefits that are independent of outcomes, accruing as part of interventions and data collection procedures, such as:

- Your blood pressure will be monitored regularly throughout your participation
- You will have a consultation with a nutritionist
- You will receive lunch, carfare and \$20 dollars on days you travel to the lab to participate
- Your child will receive a complete screening for ADHD and you will receive a list of referrals should your child demonstrate signs of the syndrome
- Your child will receive three hours of one-on-one tutoring in math from a student teacher

Often, there aren't any such benefits, in which case it is best to simply state "there are no direct benefits to participants anticipated."

Overstating benefits can be coercive. The above example is relatively innocuous, but in research involving learning and other disabilities and/or mental illness, overstating benefits can erode the vital distinction between research and treatment in the minds' of potential subjects and/or their parents and guardians.

1.2 Failure to Detail Probability of Risks

At bottom, this problem stems from a failure to conduct an adequate literature review or to cite sources in sufficient detail. It occurs most frequently in protocols that make use of standardized diagnostic and assessment procedures and instruments, such as in the example below.

Chemoreflex Control of Breathing in Fit and Unfit Individuals, Ronald DeMeersman, PI.

Original: Risks and Benefits: Participation in this study involves a **small risk of cardiac complications, sudden cardiac death or sports injury, but this risk is no greater than that an individual would experience in any other strenuous workout**. Steps being taken to minimize those risks, described in detail below, include supervision of all exercise testing by a physician and establishment of both criteria to halt a test and of an emergency plan to handle heart problems or sports injuries should they occur.

The Belmont Report defines the term "risk" as a possibility that harm may occur. However, when expressions such as "small risk" or "high risk" are used, they usually refer (often ambiguously) both to the chance (probability) of experiencing a harm and the severity (magnitude) of the envisioned harm. Here, the PI sites potential risks that may arise from subjects' participation, but does not give the probability of experiencing such adverse effects. In general, the more serious the risk, the more precise you should be about its probability:

Revised: The following was included: Previous research has reported complications from exercise testing in individuals who are not at risk for complications. The risks reported were **1 death per 10,000 tests (0.01%)**. Additional research has reported the cardiovascular complication rates of exercise testing by physicians. In one series involving more than **1 million exercise tests, there were no deaths or complications in athletes. A 13-year experiment using exercise physiologists for the supervision of exercise stress tests revealed no deaths, 4 heart attacks and 5 episodes of chest pains in 28,133 exercise tests.**

A related question that frequently arises when standardized measures are proposed is "has this instrument been normed for this particular population?" If the answer is no, cite results from the instruments use in the general and other targeted populations and make your own assessment of the probability of specific risks.

1.3 Waiver of Written Informed Consent Due to Increased Risk to Subjects

This section illustrates a point made in the introduction, that "one size fits all" solutions are not possible in human subjects protections. While written informed consent is the "gold standard" in research and should be obtained wherever possible, there are times when requiring informed consent actually increases risks to subjects by linking individuals to a specific project. In the following example, the political climate in Hong Kong could have led to career and perhaps even more serious repercussions to participants if they were linked to negative remarks, so the investigator was asked to amend her protocol, which originally included written informed consent, to the following:

Education Reform Policy and Early Childhood Teacher Education in Hong Kong Before and After the Transfer of Sovereignty in 1999, Doctoral Student PI.

Revised: Research Description: This study focuses on **how early childhood teacher education changes as a result of the actions taken by teacher educators to respond to reform policies and how the change of political context may have influenced teacher educators' responses to these policies...Informed consent will be obtained during the initial phone call or personal visit.**

The IRB made a similar recommendation to an investigator interviewing Afghan refugees in Iran about their treatment in the host country. In that case, the IRB further required that all tapes be transcribed and translated in Iran, that the original tapes be destroyed and that the investigator emailed all materials to herself prior to departure so that no project related materials be on her person when she left the county.

Ethnographic researchers may be working with populations that would greet the written informed consent requirement with hostility and thus reduce participation. Written consent here would not pose any additional risks to subjects, but it would present an unacceptably high bar to participation. Investigators may request a waiver of written informed consent in such cases.

It is critical to remember that what the IRB is waiving in these instances is simply written *documentation* of informed consent. All other requirements pertained to informed consent must still be followed, usually by obtaining consent verbally or by providing participants with a consent form that they do not need to sign and return.

1.4 Failure to create adequate provisions to handle adverse events

Another frequent concern that arises with risks and benefits is the absence of a plan to handle adverse events due to participation in the research. Such a plan should be included in all research carrying more than minimal risk after all possible procedures to reduce or eliminate the risk have been put in place. Examples of plans that are often appropriate include:

- Referrals to counselors/mental health professionals
- Presence of a nurse/health care professional/someone trained in CPR, etc.
- Referral to a school psychologist on site.
- Presence of a parent or guardian
- Presence of a bilingual interpreter to explain procedures as research is conducted

2. Confidentiality/Anonymity

The concepts of "anonymity" and "confidentiality" are often confused in research protocols; however, they mean very different things in the context of human subjects protections. Researchers much consider very carefully which is most appropriate for their own research. Anonymity means nobody, including the PI and the research team knows who the subjects are, or has any way linking coded data to a specific individual. Survey research and research where participants are identified only by a code are the only kinds of research where anonymity can be promised. You cannot promise full anonymity if you intend on getting written informed consent. While it is a fairly simple matter to design procedures that de-link individual participants from the data collected from them, written informed consent at a minimum means that should the forms be lost, stolen or viewed by unauthorized persons, individuals can be identified as having participated in a particular study, which, depending on the nature of the data collected, could cause harm. A promise of confidentiality, together with detailed procedures for keeping data and signed consent documents secure, is usually more

appropriate for most research conducted at TC. Any research plan where the investigator or any member of the research team knows the identity or can break coded data to ascertain the identity of participants, anonymity is not possible and confidentiality procedures must be devised

Most risks in social and behavioral research stem in some way from confidentiality issues, so this is the area of your protocol that will require the most attention. Below are some examples of problems that arise surrounding confidentiality issues:

2.1 Problems in the Use of Pseudonyms

In case studies and other qualitative research reports that focus on unique individuals rather than aggregated data from many individuals, pseudonyms for both people and locations are used prevent identification of participants. In the example below, the investigator fails to explain in the informed consent document that pseudonyms will be used in any publications resulting from the research, and does not explain the purpose of the procedure:

The Use of English Argument Structure Cues in English Verb acquisition by Children with Severe to Profound Prelingual Deafness, Carla Sue Feinstein, PI.

Original: How Results Will Be Used: The results of my study may be used for developing materials and techniques for teaching English verbs to children who are profoundly deaf. The research data may also be published in professional journals and/or articles.

Revised: The following line was added: [since all study participants will be given pseudonyms, **there will be no way to identify the subjects in the publication of the research data.**

This is a relatively minor point that illustrates a larger problem that surfaces frequently in protocols: a tendency for investigators to forget that procedures whose purpose is transparent to them as researchers may be unfamiliar to their research participants. There is also a tendency to forget to include procedures that seem to "go without saying" to trained researchers. The purpose of all procedures used needs to be completely explained to participants. Also, it's important you explain all procedures fully in your application. The IRB consists of members from every department and from all disciplines, so bear in mind that both standard terminology and procedures in your own discipline may be unfamiliar to your reviewers.

2.2 Confusion between Anonymity and Confidentiality

This is the single most frequently occurring error in IRB application. Relatively few protocols can be classified as truly anonymous; even if a research does not record identifiers nor includes any identifying information in any reports or publications stemming from the research, if the identities of the participant are known to any member of the research team, the research must be classified as confidential, as in the example below.

High School Girls' Positive Attitudes Toward Mathematics: A Look at the Bright Side of the Issue, Doctoral Student PI.

Original: Description of Research: These interviews will be audiotaped. The tapes will be transcribed and used in my dissertation. Your name will not be used in the study to protect your anonymity.

Revision: These interviews will be audiotaped. The tapes will be transcribed and used in my dissertation. **Your name will not be used. All transcripts and data collected will use your pseudonym.**

Web- and mail-based surveys are typically the only types of research that can be called truly anonymous; analysis of medical and/or educational records can frequently be called anonymous as well, provided that all records have been stripped of identifiers BEFORE they are released to the investigator. Also, bear in mind that any project that requires participants to sign an informed consent document must be classified as confidential rather than anonymous. Even if the project is designed in such a way so that data cannot be linked back to any individual participant, frequently the nature of the project will mean that participants are placed at risk if it becomes known that they participated in the project at all (or even in some cases were part of an eligible class of subjects).

2.3 Inappropriate use of anonymity in research design

Conducting research anonymously obviously provides the greatest protection against any kind of breach. However, just because it is possible to conduct a survey anonymously does not mean doing so is the best option. Research conducted anonymously makes it impossible for investigators to intervene if they discover information that indicates the presence of an ongoing condition, situation or behavior with the potential to harm the participant (or, in the case of criminal behavior, others). In one case, an investigator planned on administering standardized scales anonymously for depression to a group of high school students in Chinatown shortly after 9/11, which resulted in the exchange summarized below between the IRB and the PI:

Asian Immigrant Cultural Adjustment and Mental Health, Christine Yeh, PI

The scales used included questions about suicide and suicidal ideation. If a participant answered affirmatively to any of these questions, the investigator would have been unable to fulfill her ethical obligation to investigate further and make referrals. The PI recognized the validity of this concern and changed to confidential data collection and created a plan to follow-up and perhaps intervene with any student whose scores indicated a strong possibility of depression.

2.4 Overstatement of Protection of Confidentiality

Occasionally, the study population is so small or so specific that just the description of the study or the population can breach confidentiality, as in the following example:

Achieving Styles, Work Behaviors and Learning Facilitation Behaviors of Student Affairs Managers, G. Case Willoughby PI.

Original: Risks and Benefits: There are no physical risks involved in this study. Individuals will be describing their work behaviors which could have the slight repercussions (positively or negatively) if the information is assessed by their respective supervisors. **By changing names and deleting identifying information, this risk is minimal.**

The level of confidentiality that the PI offers to study participants cannot reasonably be guaranteed given the nature of the study. Published results of the study, including his dissertation, will need to provide a sense of the institutional context, which you will need to describe as either “Ivy League” or “elite private”, etc and the PI’s affiliation with Teachers College, Columbia University will make the specific institution involved transparent. Therefore, the PI must inform subjects of this potential risk before they agree to participate.

Revised: Risks in this study are minimal. As all identifying information will be removed, it is unlikely that this data could be used to prejudice others against you. Still, **given that this is a study specifically of managerial staff at Columbia University’s Office of Student Affairs, interview material will be attributed to a relatively small group of individuals. Specific identification of any one person by colleagues, management or outside parties is unlikely, but possible.**

3. Data Storage

3.1 Insecure Data Storage

One of the ways to minimize a breach of confidentiality is to have adequate provisions for storing data. No matter how well data is coded, it can be decoded if someone has access to your personal files.

AskAMentor.net: Web-based Technology Mentoring for Urban Youth, Susan Mescavage Welch, PI.

Original: Data Storage to Protect Confidentiality: **Interview and focus group guides will be kept at my home, which is locked at all times.**

Nobody knows what the living situation of a PI is, so stating data will be kept at home does not convey a strong sense of security. Keep in mind that malicious intent is not the only way data can be compromised. A stray cup of coffee can nullify data, making the time your subjects spent participating in your project a waste. In this case, the PI was asked to provide a more secure place for data storage other than her locked home. A locked drawer in a home office is sufficiently secure for most purposes.

Revision: Interview and focus group guides will be **kept in a locked file cabinet** in my home, which is locked at all times.

3.2 Eventual Disposition of Audio/Videotapes

Infants Beginning Childcare: An Examination of the Start of Infants’ Care and Education at Two Campus-based Child Centers, Marjorie Goldsmith, PI.

Original: Consent Form: You will be asked if the interview can be audiotaped. You will also be asked to be videotaped at your arrival and departure from the center...The **audio tapes and video tapes will be reviewed by the researcher and kept in her home in a secure file cabinet.**

Although the PI addresses the storage of the tapes, she does not mention when she will finally destroy the tapes. This is necessary since the tapes may be a vehicle for a breach of confidentiality should they fall in someone else’s hands.

Revision: The audio tapes and video tapes will be reviewed by the researcher and kept in her home in a secure file cabinet. **The researcher will destroy the tapes after she defends her dissertation.**

If audiotaping is done merely for full accuracy in capturing the subjects' words, transcribing the recording and destroying it immediately afterwards provides the maximum level of confidentiality. Researchers in areas such as speech, linguistics, ESL, etc., may use voice recordings to capture speech patterns, pathologies, first language interference, etc. In such cases, important data will be lost if the tapes are transcribed and destroyed; this is always the case when videotaping is used. Often, the recordings made during the course of such research have enormous value not just for the project at hand, but as classroom instructional materials as well. In these cases, investigators may seek permission from subjects to retain recordings for other uses beyond the scope of the research project provided certain criteria are met:

- Investigators should be as specific as possible about the settings and audience for foreseeable future uses of the recordings
- Participation in the research should not be made contingent on granting permission to using recordings for future uses
- In most cases, it is inappropriate to request permission to use the recordings (or any other data recorded with identifiers) for as-yet unspecified research purposes indefinitely into the future. If you would like to reserve that right, let potential subjects know that future analyses of the same data may occur in the future. The IRB can advise you whether or not reconsenting your subjects is necessary when you submit an IRB application to perform secondary analysis of data already collected.

4. Potential for Coercion (real or perceived)

The Belmont Report states, "An agreement to participate in research constitutes a valid consent only if voluntarily given...Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance." Therefore, if a subject feels coerced to participate in a study, they are not freely volunteering to participate.

4.1 Potential for Coercion due to PI's Position of Authority

Students' Perceptions of the Nature of Science and the Process of Science through a Project Based Science Curriculum, Doctoral Student PI.

Original: Research Description: **Due to my teaching of science at Cedarhurst High School, I have developed a sincere interest in the effect that this type of program has on the scientific thought of participating students. I will be conducting a study throughout the school year to examine science projects as students' images of science.**

No matter how many times or in what terms a classroom teacher reassures his or her own students that participation is voluntary and that choosing not to participate will have no effect on his or her final grade, students will still perceive pressure to participate if their classroom teacher asks them to. This PI was asked whether there were other science classes at her school from which she might draw her subjects. Since there weren't, the PI was asked to describe how she would ensure that participation will not adversely affect the grades of subjects who wish not to participate.

Revised: (From Consent Letter): Students are not required to participate in this study and refusal to participate will not jeopardize their grade or status in the Science Projects/Quest program. **To ensure that students' grades are not affected, Mr. Seyfert, the science projects coordinator, will monitor the progress of all science projects classes and grades of participants and non-participants.** Students may withdraw from participating in this study at any time.

As one might imagine, this issue comes up frequently here at Teachers College. Other options for resolving the coercion issue include making a third party responsible for recruiting participants, obtaining consent from parents and/or collecting data as appropriate. If the project involves only analysis of schoolwork your students will be performing anyway, ask for permission to use the schoolwork only after grades for the term have been submitted. The issue is most difficult to resolve in projects involving new or experimental curricula. In these cases the right of the teacher (or principal, superintendent, etc.) to impose any curriculum he or she sees fit comes in direct conflict with all research participants' right to refuse to participate or to withdraw from a study once it begins. In such cases, where students can't opt out of the curriculum without jeopardizing his or her grade, the best strategy is to cast the study as a curriculum evaluation project that gives students and/or parents the opportunity to opt out (without penalty, of course) of having their classroom work included in the study and or/decline to participate in interviews or surveys about their classroom work that are not an ordinary part of instruction. Another option is to request permission to analyze classroom work only after a final grade has been submitted (with identifiers removed where possible).

Even when working with students other than one's own, there are still potential coercion problems. If you plan to recruit in classroom, try to do so in such a way that the instructors don't know who elects to participate and who doesn't. If research is to be conducted during normal class time, make sure students in the class who choose not to participate or haven't gotten parental consent to participate have an alternate activity.

Like students in teacher training programs, students enrolled in programs in the Counseling and Clinical Psychology, Health and Behavior Studies, etc., may already be working professionally in their field and develop their research questions out of their daily work. Such studies can present some thorny ethical dilemmas, especially in social service settings where clients may feel compelled to obey anyone in authority or believe that participation might help their standing within the agency. The following example, which also includes an exceptionally high level of risk to participants if confidentially were breached, illustrates this point:

Predictors of Treatment Adherence Among Parolees Infected with HIV, Doctoral Student PI.

Original: Research Description: **Participants will be informed of the study by clinic staff. I work at the Clinic as a registered dietician and health educator. I have access to their medical charts and lab data.**

The application did not included sufficient information about the institutional setting of the research site. The PI needed to describe in full the nature and the work of the Clinic and her role within it. The PI needed to describe the steps she will take to ensure her subject pool's choice to participate is free from all real or perceived threats of coercion, to which a population of parolees

would be particularly vulnerable. The IRB and the investigator were unable to resolve the issue; however, external circumstances that forced the investigator to recruit subjects from another facility, where she was not employed, helped minimize the problem considerably. Potential participants were still informed by the clinic staff, who now had no way of knowing who decided to participate and who did not. Finally, to provide the maximum level of reassurance to potential subjects, the IRB required the PI to obtain a certificate of confidentiality from the National Institutes of Health, for any research project that needs the added protection, even if NIH does not fund the project (further info. available here: <http://grants1.nih.gov/grants/policy/coc/index.htm>). The benefits of the Certificate to participants were explained in the revision to the consent form below:

Revised: **A Certificate of Confidentiality will ensure that sensitive information will not be disclosed to their parole officers, even by a court subpoena. This certificate will cover all data collected in the study (including the screen), regardless of whether I analyze the data in my findings.**

5. Justification for Excluding Classes of Subjects

The Belmont Report defines the term justice as “the sense of fairness in distribution or what is deserved.” In research, this translates into the notion that everyone who could potentially benefit from the research is represented in the subject pool. Therefore, if a certain class or subjects is excluded from the subject population a scientific justification needs to be provided.

5.1 Scientific Justification for Selection of Subjects

Executive Functions in Male Adolescents in Recovery from Alcohol & Marijuana Use, Doctoral Student PI.

Original: Description of Human Subject Population and their Involvement in the Research; This study will involve 40 English-speaking male adolescents who range in age from 16.0 to 20.11, of **primarily African American and Latino backgrounds and low socioeconomic status.**

The PI was asked to provide a scientific justification as to why she is limiting her study to African American and Latino males.

Revised: The following line was added: **Based on a preliminary survey, the typical population breakdown [of adolescent males in recovery from Alcohol and Marijuana Use] is as follows: African American, 5-%; Latino 40.9%; Caucasian, 9.1%.**

For investigators who already work in a professional capacity in their field doing research related to their job, the decision to include/exclude classes of subjects may be driven by the demographics of their students, clients, etc. This in and of itself is not sufficient reason for inclusion or exclusion of classes of people. You will also need to demonstrate that the study population possesses unique characteristics that warrant studying them in isolation from the general population or that the population was chosen in order to control for certain variables.

Often, inclusionary and exclusionary criteria are based on the presence or absence of a medical or psychological condition. A common error in such applications is a failure to include detailed information on the screening process to be used. In projects of this type, the screening process can pose more of a risk to participants than the research itself, since it requires disclosure of private health

information. If your research involves a screening procedure of this type, be sure to consider the following considerations, and address those that are applicable to your study in your IRB application:

- You must have authorization to review medical records if your project requires such a review. If not, a third party who has such authorization should make the initial contact with potential subjects.
- If your project requires administering a diagnostic of any sort, your application should include information on your qualifications to administer it and to interpret the results. If you don't have the necessary qualifications, your application should include provisions to work with somebody who does.
- If the results of any diagnostic have the potential to reveal a previously unknown illness or condition, your application should include provisions to address that possibility. These may include referrals to medical, mental health or other professionals, literature on the illness or condition made available, and a plan of action if the news of the diagnosis proves upsetting to the individual.
- All the data reviewed or created as part of the screening process must be treated with the same respect for confidentiality as the research data. This includes creating plans to safeguard the data and dispose of it after recruitment is finished.

6. Duration of Participation

The researcher needs to disclose all terms of participation, including the amount and period of time the subject will be participating in the study.

6.1 Need to Detail Full Time Involvement

Fat, Beauty and the Construction of the Female Body: Giving Voice to the Lived Experience of Fat Women Through a Search for and the Creation of Sites of Resistance to Fat Phobia, Lori Levan, PI.

Original: You are invited to participate in my research project where you will **attend 4-6 workshops** in which we will generate discussion about these issues as they relate to our own experiences as fat women or men or fat admirers.

The consent document mentions that participants will attend 4-6 workshops, but the time of each session is not mentioned. The PI was asked to fully detail the amount of time subjects will be participating in the study.

Revised: You are invited to participate in my research project where you will attend 4-6 workshops **over a period of 6 months (three hours in length each)** in which we will generate discussion about these issues as they relate to our own experiences as fat women or men or fat admirers.

6.2 Failure to Disclose Follow-up Study

Racial Identity, Treatment Motivation and Retention in Black Substance Abusers, Doctoral Student PI.

This study required a follow-up to the intervention one month afterward.

Original: Description of Research: This study involves filling out **two questionnaires**, the TMQ and the BRIAS, and a **background information sheet**.

The informed consent document does not mention the follow-up study the PI is planning on conducting, and is therefore not disclosing the full amount of time the subject will need to participate.

Revised: This study involves filling out two questionnaires, the TMQ and the BRIAS, giving background information, **and checking on your enrollment in treatment thirty days later.**

7. Use of Jargon

One of the ways to ensure the voluntary participation of the subjects is to make sure that it is in language that the subject can understand. Two ways to ensure this is by writing the consent document for adults, keeping language at an 8th grade reading level, and by avoiding all jargon. If you use acronyms, make sure to give the full name of the entity/organization/etc. which the acronym represents the first time it's used. For studies involving minors or other populations with literacy issues, the reading level should be adjusted to meet the needs of the relevant population.

7.1 Avoiding Scientific Jargon

Boehm 3 Preschool Version: The Development of the Tactile Test, Doctoral Student PI

Original: Description of Research (consent form): Your child is invited to participate in a research study that will **develop a tactile version** of the Boehm 3 Preschool Assessment: Test of Basic Concepts. The assessment tool will focus on the **comprehension of basic relational concepts that are presented in a tactile manner.** A tactile version of the test will be presented to your child to determine if the modifications make to the Boehm 3 Preschool assessment are valid.

The consent form is full of technical jargon that a layman would not be able to understand. The PI was asked to put the parental consent form in layman's terms so that parents can make an informed choice as to whether or not their child should participate,

Revised: Your child is invited to participate in a research study that will develop **a raised line/tactile version** of the Boehm 3 Preschool Assessment: Test of Basic Concepts. The assessment tool will focus on the comprehension **of basic relational concepts like near/far, top/bottom, and up/down, and will be presented as raised line drawings or images.** **The raised line, or tactile version** of the test will be presented to your child to determine if the modifications made to the Boehm 3 Preschool assessment are valid.

8. Problems related to the Research Description and methodology section.

Most of the problems in this area tend to come from condensing a long research proposal into a paragraph or two. They are relatively easy to resolve, but come up rather often:

- Failure to fully explain the research question, the exact data that will be collected and/or what will count as the success or failure of any intervention.
- Failure to include surveys, questionnaires or interview protocols developed specifically for a particular protocol.
- Failure to include a rationale for a control group or to clarify the differences between a control and a treatment group.

9. Consent Form Problems

The research description section of the informed consent template is the section of the proposal that receives the most scrutiny during the review process. Some of the points below have been touched upon above, but bear repeating here:

- Consent forms are written in language beyond the recommended level of readability, or are otherwise too complex for the target audience.
- The description of the time involvement and procedures to be followed are not as detailed as in the five-page protocol description.
- If the study requires a control group, participants need to know they may be assigned to one. Offer the treatment/training/instruction, etc. to anyone in the control group who might wish to receive it after the study is completed if it is possible to do so.
- If the research description is being used to obtain parental consent for a child's participation, "you" is changed for "your child" as appropriate throughout.
- Be mindful of the fact that even if English proficiency is a requirement for a child to participate in your research, the child's parent or guardian may not be English proficient and translations of the parental consent forms may be necessary.
- The section of "Participants' Rights" Page concerning audio and videotaping may be omitted if those procedures will not be used.

10. Final Words

Most other issues that may delay the IRB review process stem from failure to follow the IRB application procedures detailed on our website and within the application itself.

The IRB strongly recommends that you leave ample time for the review process – especially if you will need to obtain IRB approval or permission(s) from other institutions or organizations.

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OSP gratefully acknowledges the generous permission of the TC faculty, students and alumni who have allowed their work to be excerpted for this publication. When an example appears without a PI name, OSP was unable to contact the PI to get active permission to excerpt from his/her application.