

## ***A Student's Guide to Navigating the IRB: How to Successfully Navigate a Potentially Overwhelming Process***

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### ***Abstract***

Graduate students must complete a research project to receive their degree. In addition to this basic requirement, the student may be required to submit a research proposal and application to the governing Institutional Review Board (IRB) for approval prior to beginning the research project. This article describes the IRB process and offers tips for successful navigation of the procedure.

### ***A Student's Guide to the IRB: How to Successfully Navigate a Potentially Overwhelming Process***

I did it! I got into graduate school. Initials were eventually going to follow my name! My parents and my grandma were so proud. I knew I could handle the class work, and I was excited about the prospect of doing a real piece of research. I was on my way, but what I did not know was the obstacle that lay ahead.

Excited and nervous, I entered my first thesis meeting with my advisor. We discussed several possible research topics and after a lot of reading, thinking, and a couple more meetings discussing that reading and thinking, I settled on a topic. I was going to investigate the potential usefulness of Functional Assessment in determining the maintaining contingencies of non-contextual speech (sometimes called delayed echolalia) by children with autism and autism spectrum disorders. A research proposal was in my future. As my advisor discussed my writing plan, he began to drop some unexpected initials: IRB. Apparently, my advisor was not the only person from whom I would need permission to begin my investigation. These mysterious initials, IRB, were also going to review and assess my proposed investigation. It seemed that their approval was more important than my advisor's. Yet, I still did not know who or what the IRB was. As a result of my experience, I write this paper in the hopes of helping other students who are faced or will be faced with the mysteries of the Institutional Review Board a.k.a., IRB.

## *What Is the IRB and Why do I Need Its Approval?*

Within the U.S. Department of Health and Human Services, lies the Office for Human Research Protections. This body governs all Offices of Research within every research institution in the United States. These research institutions include universities, public and private hospitals, clinics, and other organizations conducting research with humans. Safeguards were created for Human Subjects as a result of ethical concerns about “the preservation of autonomy, beneficence, nonmaleficence, and justice pertaining to research in human subjects” (Colt and Maynard, p.1605). It is unlawful for research practices not to meet the guidelines set forth by the Office of Human Research Protections (Bronte-Tinkew, Allen, & Joyner, 2008).

Within the Office of Human Research Protections lies the reason why student researchers must receive permission from their educational institutions to conduct research. Receiving permission to conduct research means that the research protocol you, as the student researcher, have written has been thoroughly reviewed using the guidelines set forth by the Office of Human Research Protections. These guidelines protect your participants’ safety as well as protect you as the researcher from liability in case something goes wrong in your study. Participants will receive information about your study that enables them to determine whether they want to participate or not; this information must be written at their level of understanding (Skarbeck, Henry, & Parish, 2006, Kennedy, 2005). In addition to the guidelines that exist for research protocols involving adult participants, specific guidelines (derived from Public Law 106-310) exist for research protocols involving child participants. A parent must give consent for a child under the age of 18 to participate however you may also explain your research to a child participant over the age of 6 and ask them to agree to be a part of the study (Skarbeck, Henry, & Parish, 2006). Each institution’s Office of Research enforces these guidelines.

Offices of Research take on different names within different research institutions, all derivative of the Office of Research. However, the name does not change the responsibilities of each office. Each institution’s Office of Research is responsible for overseeing all aspects of research within the institution including integrity and responsible research practices. Different departments within the Office of Research govern these differing aspects of research (e.g., Biomedical, Animal Science, and Social Behavioral). The IRB oversees the latter of these; ensuring responsible research practices.

IRB stands for the Institutional Review Board. The Institutional Review Board is the body within a research institution charged with reviewing all proposed research protocols to ensure each meets the guidelines set forth by the federal Office of Human Research Protections. The IRB is usually organized into departments according to content area. Large research institutions often have some of the following IRBs, Biomedical Institutional Review Board, a Cancer Institutional Review Board, and a Behavioral and Social Sciences Institutional Review Board. IRB members consist of faculty and other institutions staff who sit on the board and review research proposals on a predetermined schedule using the guidelines set forth by the corresponding IRB. Your research advisor will help you determine which IRB should review your research protocol.

Information specific to your research institution may also be available via the Internet. Additionally, you may find that your advisor has received prior IRB approval via a grant-writing process. If this is the case, then your advisor will help you proceed under the terms and conditions of the ruling grant. Assuming that no prior approval has been received, you will need to take part in the IRB review process and submit an application.

### *Application and Review Process*

The student and his/her advisor are responsible to report research projects to the appropriate IRB. You are required to wait until you receive approval notification from the IRB before you begin any part of your research. The IRB application and review process is as follows (see Figure 1).

1. Develop research topic with your advisor
2. Write and obtain approval from your advisor for your research protocol
3. Determine appropriate IRB review application (exemption, expedited review, or full review)
4. Submit IRB application and research protocol
5. Respond to IRB with necessary revisions or with acknowledgement of final approval of research protocol

In general, you will find three different types of applications: exempt, expedited, and full, for presenting your research protocol to the IRB (Lynn & Nelson, 2005). The first step is to determine what level of review your protocol requires. It may qualify for an exemption from the IRB Review. The purpose of the exempt process is to identify short-term research projects that pose a low-level risk to the participants. Projects that usually qualify for exemption take three forms, surveys, typical classroom activities (e.g., note-taking), and chart reviews. Using the Guidelines for Exemption from IRB Review, you are provided with a list of questions regarding the nature of your work and the involvement of your participants. The exemption application is usually reviewed by an IRB staff representative who will provide you with relatively immediate feedback. At this point, if your application is approved, you will be free to begin your research. If you do not qualify for the exemption, you will have to file one of two types of applications, expedited or full review, to the governing IRB.

The next review process is the expedited review. This application can be found at your IRB. The application begins with a series of questions to help you determine whether your protocol qualifies for the expedited review process. If so, fill out the rest of the application and submit to the appropriate IRB per application instructions. The expedited application does not go to a full board meeting for review; a senior level reviewer of the IRB will review your application. Since only one person reviews the expedited applications, they are usually reviewed more quickly. However, the timeline on the turnaround for this application varies depending on the availability of the senior reviewers. Once you are notified of your approval you are free to begin your research. If you do not qualify for the expedited review or your application is disapproved, it will be necessary to fill out a full review application if you wish to continue with your research.

The application for IRB Review is necessary for research protocols that require a full review by the review board. This application requires detailed responses to specific questions regarding your protocol and the risk it will pose to the participants of your study (Kennedy, 2005). Instructions are provided on each application on how to answer the questions and how to submit the application and your protocol to the appropriate IRB. Following your submission of the full application, a staff reviewer will briefly review your application for completeness. The staff reviewer will inform you if your application is missing any necessary components. Once the staff reviewer has determined that your application is complete, he/she will send the application to the board meeting. Usually, the board will meet 1-2 times per month to review full applications. The response of the board to your application will take one of three forms: (a) approved, (b) approved with conditions, or (c) disapproved.

- **Approved.** Full approval from the IRB means that you may start your research immediately. IRB approval for the study is based solely on the protocol that you submit. If you decide that major changes must be made to the protocol to answer your research question then you must submit these changes to the IRB for approval prior to implementing the changes. Major changes could include items such as modifications made to the population of participants or to the measurement tools you are going to use. Minor changes could include brand of materials used within the study or a 1-minute time change in the amount of time students are given to complete their work. Your advisor will help you determine what constitutes a major change in protocol. The approval is usually good for 1 calendar year. At which point, if the research is still being conducted or the data are still being analyzed, then an extension application must be completed and submitted to the IRB.
- **Approved With Conditions.** If approved with conditions, the board will provide you with a list of conditions that specify modifications that should be made prior to full approval of your protocol. It is common to require the researcher to provide evidence that the necessary modifications have been made (e.g., phone scripts, consent letters, and revised data sheets). After these modifications, as stated by the conditions, have been submitted, the IRB will review again and determine whether the modifications meet guidelines for final approval.
- **Disapproved.** If disapproved, you must critically analyze your research protocol, the risk to your participants, and the answers to your application questions. The IRB will usually provide a list of reasons for the denial. In the event of a disapproval, it is good practice to make the necessary and recommended modifications to your research protocol and respond to application questions and to resubmit your entire application. The major difference between a disapproved application and one that has been approved with conditions lies in the resubmission of the modifications (Fiske, 2009). To respond to the disapproved application, you must submit a new application in its entirety.

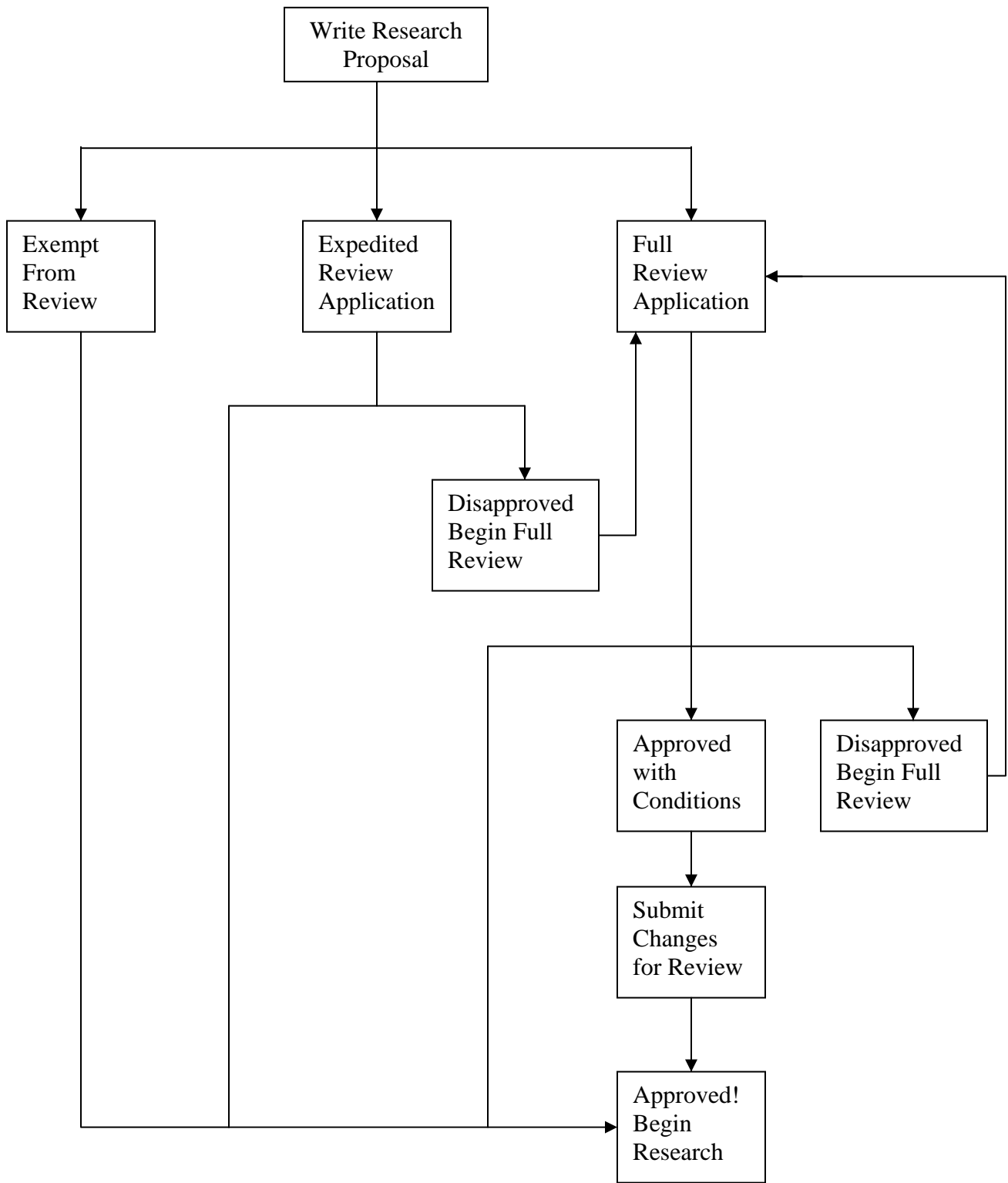


Figure 1. IRB application process.

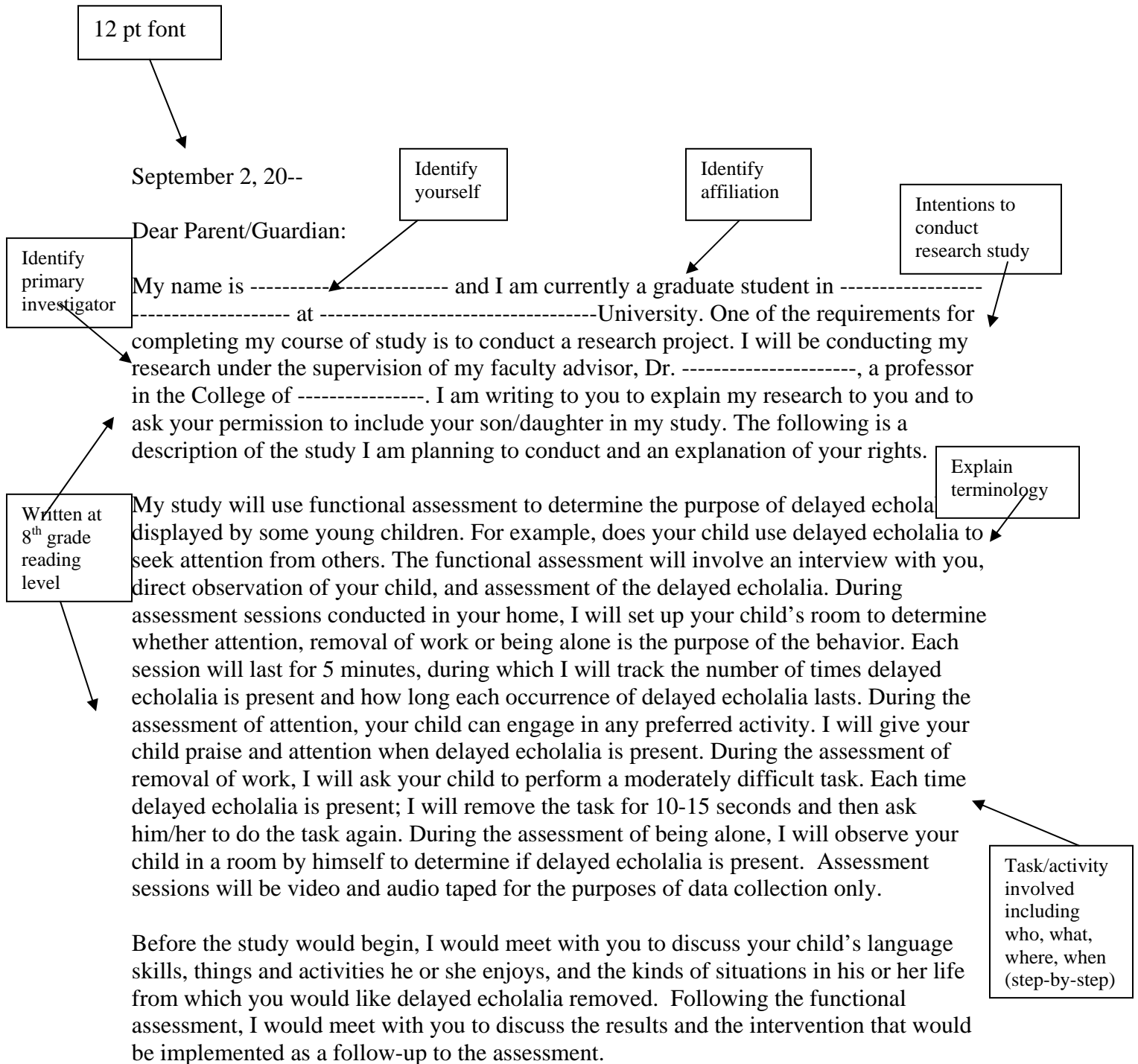
Here are some tips on completing your corresponding applications:

- ***Start early.*** An initial response from the IRB could take 3-5 weeks. Final approvals usually do not come until 2-3 reviews of your application have occurred. Applications are reviewed in the order they are received so plan accordingly. Most review boards do not have a “rush” status if you are trying to graduate.
- ***Ask questions before you begin writing.*** Emailing questions to the designated IRB representative has become an increasingly efficient means of communicating questions and concerns specific to your application. The more detailed you can be in your questions the more likely you will receive a helpful response and the less likely you will receive an answer of, “It depends.”
- ***Read the directions.*** Each application comes with a set of instructions that should be diligently followed when completing the application.
- ***Detail the methods section.*** The review board, to ensure that there is no danger to the participants in your study, will critically analyze the methods section of your research protocol. Detail is very important in this section. Ask another person to read the methods section and act out the procedure. If he/she has questions regarding the procedure, then you should rewrite this section of the methods.
- ***Take care when writing consent letters and recruiting material.*** Consent letters and recruiting materials, including phone scripts, are an extremely important part of your application. Consent letters outline the research purpose and procedures in everyday, non-technical language. Additionally, consent letters detail the rights of each person as a participant in the research study. See Figures 2 and 3 for examples of recruitment and consent letters.
- ***Keep your advisor informed.*** You should always check with your research advisor to ensure you are taking the necessary precautions to protect your participants and yourself.
- ***Notify supporting agencies.*** It is important to obtain support and approval from other governing agencies if necessary. Participants may come from a variety of different environments including school districts, hospitals, or clinics. In using these participants, you must report your proposed research to each institutions office governing research practices. This means that you may have to apply to multiple IRBs before beginning your research.

The IRB process can take anywhere from 2 weeks to 6 months (Lynn & Nelson, 2005). The timeline can vary based on your application. If you answer each question completely and provide enough detail that the board can make an informed decision then the turnaround time on your

application will be shorter. Putting extra time and care into your application at the start of the process can significantly reduce the amount of time the entire process will take. It is necessary to allot enough time to receive approval to conduct your research, but also to allot enough time to be able to conduct your research. You do not want to 'cheat' research because you received your approval too late to complete your entire study.

Figure 2. Sample recruitment letter





Rights of participants

Your son/daughter would be involved in the assessment for approximately 30-minutes, three to five days per week for approximately 2 weeks. You are not in any way obligated to grant permission for your child to participate in this research, and your child will not be penalized in any way for not participating. If your child does participate, you have the right to withdraw him/her from the study at any time without prejudice to you or your child. During any session, if your child asks to stop or shows signs of wanting to stop, the session will be terminated. Please be assured that your child's name will not be revealed in any publication, document, recording, computer storage or any other form of report or presentation developed from this research.

Session termination

Attached are two copies of the assessment consent form. By signing this consent form you grant permission for your child to participate in the assessment part of this study. You should return a signed copy of the consent form in the stamped, return envelope and keep the second copy for your records. During the meeting to discuss the results of the assessment, I will provide you with 2 additional consent forms concerning the intervention phase of this study. At that time, you will not in any way be obligated to grant permission for you child to participate in this research, and your child will not be penalized in any way for not participating. If you have any questions regarding this research or your rights related to participation in this research, feel free to call me at home at (###) ###-#### or call Dr. ----- at (###) ###-####. If you have questions about your child's rights as a research participant, you can call the Office of Research Risks Protection at (###) ###-####. Thank you for your cooperation.

Sincerely,

Contact Information

Enclosures: 2 copies of Consent Form for Participation in Educational Research  
Self-addressed stamped envelope

Figure 3. Sample consent form.

Form for Participation in Educational Research

I agree to allow my child to participate in a research study evaluating the effects of social praise on delayed echolalia. Ms. ----- will conduct this study under the direction of Dr. ----- . The nature and purpose of this study have been explained to me, and I understand that instructional sessions will require approximately 30 minutes, five to seven times per week for approximately 12 weeks.

I also grant permission to Ms. ----- and Dr. -----to video and audio tape the research sessions for data collection purposes and to obtain test scores and other information from the ----- Autism Program to describe my child's disability and current level of functioning for the purpose of writing the research report. I understand my child's and my own identity will not be revealed to anyone not directly involved in conducting the research, or by means of publication, documentation, computer storage, or any other form of report developed from this research. Additionally I understand I may withdraw my consent for participation at any time. If I have any questions with regard to this study, I can call Dr. ----- at (###) ###-#### or ----- at (###) ###-###. If I have questions about my child's rights as a research participant, I can call the Office of Research Risks Protection at (###) ###-####.

\_\_\_\_\_  
*Child's Name*

\_\_\_\_\_  
*Signature of Parent or Guardian*

\_\_\_\_\_  
*Date*

-----  
*M.A. Student Researcher*

\_\_\_\_\_  
*Date*

\_\_\_\_\_  
*Professor and Faculty Advisor*

\_\_\_\_\_  
*Date*

### ***Tips for Successful Navigation***

***Ask your advisor.*** Your research advisor is a resource. More than likely, he or she has been through the research process many times before. Attention to detail is very important and your advisor can help you with ensuring the completeness of your protocol and that you have used the most appropriate wording.

***Check due dates.*** Find out the IRB review schedule and set timelines. Review boards usually meet on a set schedule, either bi-monthly or monthly. Often the date that a review board meets is not the date that your application is due. Your application is due prior to the board meeting date. To ensure that your application is reviewed on the date of your choice, you should have your application in at least one week prior to the application due date.

***Be thorough.*** Follow every instruction in the application. Often guidelines are provided regarding the information necessary to include in response to application questions. Utilize the checklists that accompany the application. These checklists will help ensure that you do not skip parts of the process.

***Duplicate everything.*** Keep exact copies of all correspondences with the IRB. Additionally, provide both your advisor and family/friends with copies of your application. This precaution will prevent total loss of your work in the face of natural or technological disasters.

***Schedule extra time.*** Try not to schedule anything for the day you submit your proposal to the IRB. Submit your proposal in the morning so that if you are told that you need to make more copies you have time to do so. Once you have completed submitting your application, take the afternoon off and do something nice for yourself. This will be a big accomplishment and you should take some time to relax, but not too much!

***Ask for a receipt when submitting your application.*** The receipt should contain a listing of the items you submitted, the date and time you submitted, and the signature of the person who received the materials.

### ***What to Do While You are Waiting***

It is important to make sure that during every step of the process you are productive including while awaiting a response from the IRB. The following will help you be prepared to implement your proposal immediately upon receiving the happy news regarding the approval of your study:

1. Begin gathering materials that you will need to implement your protocol.
2. Set up training timetables for training primary and secondary data collectors as well as any people (parents, teachers, or peers) that will be implementing the research procedures.

3. Continue to work on your literature review. The application process could take up to 6 months so it is necessary to keep up with current research so that you have a complete literature review.
4. Keep in contact with staff that eventually will be involved in implementing your research. Teachers, aides and principals should be aware of the status of your application.

### *Conclusion*

The IRB process can seem daunting and overwhelming but keep in mind that thousands of students have successfully navigated this process and you can too! Do not be afraid to ask questions. Ask your advisor, ask former students, ask current students, and talk with your peers who are going through the same process. Use the Internet to find answers to questions you might have specific to your institutions' IRB. Additionally, you may find guidelines and tips from your institution that will help you along the way.

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