LittleStar RRC Proposal Review & Discussion Template

1. Why is the study being done? What data are presented to support that reason? Does it make sense to you?
2. Can the study aims be answered given the way the study is designed?
3. What procedures will be used with the subject only for reasons relating to the research? Do they all seem necessary?
4. Of the procedures that are being used for research reasons, what are the foreseeable risks associated with them? Can you think of ways to lower the risks?
5. What is the possible benefit, if any, that a subject may receive by participating in the study? Is the benefit "worth it", given the risks involved? What about possible risks to society as well?
6. If you were a potential subject, would you understand the consent form and what is expected of you if you agreed to participate? Could you explain the study to someone after reading the consent form?
7. Are the descriptions of study procedures in the consent form and in the research protocol/study description identical?
8. Who is being included in the research? Who is being excluded? Does it seem fair? Ethical? Safe? Does the study target the appropriate population based on fairness, safety, and ethical considerations? Populations of convenience should be avoided. For example, investigators should not target patients on their caseload just because of "easy access," or a population that will not benefit from the research. Is the selection free of coercion? Is there an authoritative relationship between the person who is recruiting and the potential participant, such as BCBA/Patient or Supervisor/Supervisee?
9. Have procedures been put into place to minimize possible coercion?
10. Are there folks being included who you would consider to be vulnerable (children, elderly, cognitively impaired)? Do the researchers explain additional protections they have put in place for them?
11. Does the study address how the subject's participation and data obtained from the study will be kept confidential?
12. How is the privacy of the subject taken into consideration? For example, does the consent discussion take place in the clinic, or in a private setting?
13. For more than minimal risk studies, does the study address how the data will be monitored to ensure the safety of enrolled subjects? For example, do the investigators propose to have an independent, 'real time' analysis of the data performed to assess are responding? Are termination criteria clearly outlined? Or, perhaps the study's risk/benefit analysis is acceptable for approval, but the IRB would feel more comfortable reviewing the data themselves after a certain period of time, or after a certain number of subjects has been run.