Twenty questions every IRB should ask before approving therapeutic clinical research.

1. Is the trial design the best possible design from an ethical perspective?
2. If the trial design involves dose escalation or randomization, are these elements critical to the scientific validity of the results?
3. Is this particular trial necessary? Will it advance science or medicine?
4. Will there be a question as to whether the patients have given true informed consent?
5. Who will be involved in the informed consent process and how long is it anticipated such a process will take? Will the information provided be complete and will it be completely understood?
6. Could there be reasons that consent will not be fully voluntary?
7. Will the patients be coerced either by their illness or by their lack of alternatives?
8. Will the investigator also be the patient's physician?
9. Will participation in the trial be in the patient's best therapeutic interest? Has the patient been offered the best available palliative care as an alternative?
10. If this is a double-blind placebo trial, is there a scientific basis for each blinding? Is there a risk of either the researcher or the subject believing results are beneficial or are such results objective and incapable of being shaped by bias? Is there a standard therapy available which is superior to placebo? Is there a risk of harm if the patient randomized into the placebo arm receives no therapy during the placebo phase? Will the patient understand the basis of his or her randomization?
11. Will the patient understand that his or her dose will not necessarily be adjusted on the basis of the patient's needs?

12. What principles of justice or fairness are being used in selecting patients?
13. Will the patient know about his or her right to terminate participation at any time? Will such termination be technically or practically possible?
14. Once the trial begins, will there be ongoing communication with the patients and the IRB about adverse events or any other results? Who will be personally responsible for this continued communication?
15. Are there any conflicts between the interest of the researcher, the presumed interest of the patients and the actual expressed interest of the patients?
16. Is the researcher motivated to do the specific research either by financial considerations or by professional pressures and deadlines?
17. How will these conflicts of interests be handled? Will they be discussed with the patients?
18. Is the investigator's definition of success or efficacy in conflict with the patients' definitions of quality of life?
19. Are health index profiles or checklists being used in communicating with the patients? Will the patients be aware of the possibly limited prognoses for full recovery?
20. What will the patients expect from participation in the trial? What will the institution expect from conducting the trial? What will the sponsor expect? What does the researcher expect?