

Frequent reasons why protocols are sent back for changes (modifications or deferral):

1. The NTRP is too technical for a lay person to understand (often because it was a Copy & Paste from the Sponsor's Protocol)
2. The informed consent documents is/are written in a way or at a level that is too technical for a lay person to understand
3. The risks of the study intervention are unclear
4. The recruitment and/or consent process is unclear, inadequate or contradictory to what is included in the application and/or protocol
5. It is unclear if the subjects are able to give consent due to possible cognitive impairments
6. The inclusion/Criteria are not adequately specified
7. The information outlined in the protocol application or Sponsor's Brochure does not match the information in the informed consent document(s)
8. It is unclear what the alternatives to participation are.
9. It is unclear what the standard of care is for a particular subject population/disease
10. It is unclear if the procedures and/or samples being collected are being done for standard of care or for research purposes only.
11. It is unclear in the protocol and/or consent document(s) whether or which procedures will be billed to the subject
12. The randomization procedures and/or study design is unclear
13. The statistical plan is inadequate or unclear
14. It is not clear whether the drug or device is FDA-approved
15. Imaging procedures not properly described and/or the risks are unclear
16. It is not clear what entities will have access to the data and/or it is unclear how the data will be stored and confidentiality protected
17. The Data Safety Monitoring and/or Stopping Rules not adequately described
18. Plans for handling psychological distress/psychiatric referral are not adequately described
19. Specialists performing procedures as part of the research intervention are not included on the list of Investigators and/or it is unclear if the Investigators listed have the appropriate privileges to perform procedures
20. The titration or frequency of drug administration is unclear or questionable in the protocol or consent document(s)
21. The study does not appear to consider emerging data from the field that have implications for the current study (AE, IB, new drugs, meta-analyses), or the investigator does not cite literature in favor of the intervention
22. Studies involving WCMC/NYP Employees or Students do not adequately describe how they will be protected from coercion and/or breaches of confidentiality
23. For continuing reviews: Failure to provide crucial information at the time of renewal (Preliminary Findings, Low enrollment, AE Table, etc.)
24. WCMC's and/or NYP's involvement in the study is unclear
25. There are confidentiality issues between minors and their parents (child abuse, pregnancy, drug screen etc) that need to be addressed