Red Flags to Look For When Reviewing Protocols

1. Are the 111 Criteria Met?
2. Does the study team expertise match that needed for the study?
    a. If an interventional study, is there an MD on the team?
    b. If vulnerable populations are the target, is there the expertise with this group on the team?
3. If vulnerable populations are included in the study:
    a. If not the targeted study population, are they needed in the study?
    b. Are risks minimized?
    c. What risk level for children & number of parent signatures?
    d. Have criteria for studies with prisoners been met?
4. Is placebo use justified & appropriate?
5. FDA issues:
    a. Is the IND # & FDA Correspondence included?
    b. Is the IDE # included?
    c. Does the IRB need to make a significant risk/non-significant risk determination for a medical device?
6. Is a Certificate of Confidentiality needed? Will they be applying for one?
7. If an international study…
    a. Does the team have experience in that country & culture?
    b. Are they partnering with a local organization?
    c. Do they have local IRB approval?