## CHECKLIST FOR REVIEW OF CONSENT FORM

1. Is the consent form printed on appropriate PARKER UNIVERSITY stationery?
2. Is the consent form written in a consistent form ("I, me, my..." instead of "I, you, we")?
3. Is the language written at the appropriate level?
4. Is each element (or appropriate combination) of informed consent identified by a subheading in BOLD TYPE?
5. Is the scientific title of the study present at the top of the consent form?
6. Is there a clear statement of the purpose of the research?
7. Is there a description of the study design (e.g., longitudinal, single-blind, placebo), method of subject assignment to groups (e.g., randomization) and probability of assignment?
8. Is the description of potential risks and discomforts adequate?
9. Is the statement of potential benefits adequate?
10. Is there a statement concerning alternatives to participation (required for therapeutic studies)?
11. Is the description of potential risks and discomforts associated with therapeutic alternatives adequate (therapeutic studies)?
12. Are the financial obligations of the subject clearly stated?
13. Are any economic incentives/rewards for participation clearly stated? If none, is it so stated?
14. Is the assurance of confidentiality clear and complete?
15. Is the standard FDA Access to Research Records Statement present (for FDA regulated studies)?
16. Is the appropriate standard Compensation In Case of Injury Statement present (more than minimal risk studies)?
17. Is the standard IRB Subject Withdrawal Statement present?
18. Is there an offer to answer all questions?
19. Is the standard IRB Concluding Consent Statement present?
20. Are there dated subject and investigator signature blanks?
21. Is there a witness signature blank (more than minimal risk studies)?
22. Is the name and office telephone number of the investigator placed at the end of th consent form?
23. Is the night/home telephone number of the investigator present (more than minimal risk studies)?
24. Is there Parental Consent and Child/Youth Assent clearly described (studies involving minors)?
25. Is there a description of each procedure to be applied to human subjects and how often i will be performed?
26. Is there identification of the individual(s) who will perform the procedures and/or interact with the subject?
27. Is there a statement of where the research will be conducted, when the research will be conducted, and how much time (per session/in total) will be required of the subject?
28. Is there a statement concerning any medications, therapeutic regimens, foods, or other substances that are contraindicated/disallowed either before or during participation in the study (eg drug "washout')?