

WAKEMED
INSTITUTIONAL REVIEW BOARD

CHECKLIST FOR PRINCIPAL INVESTIGATORS

This checklist has been developed in an attempt to reduce the number of studies returned because essential items are missing. If elements do not apply to your particular study, indicate NA in the blank.

Please use this checklist prior to submitting studies to the IRB office and **RETURN IT WITH YOUR APPLICATION.**

1. Title of Study: _____
2. The Principal Investigator has signed the application. _____
3. The Faculty Sponsor has signed the application (if applicable). _____
4. The Department Chairman has signed the application. _____
5. The Department Chairman has checked appropriate designations. _____
6. Attached Curriculum Vitae:
Principal Investigator _____
Co-investigator(s) _____
Clinical Coordinator(s) _____
7. Certificates for Education Training in Protection of Human Research Subjects
Principal Investigator _____
Co-investigator(s) _____
Clinical Coordinator(s) _____
8. Conflict of Interest Financial Disclosure Form is attached.
Principal Investigator _____
Co-investigator(s) _____
Clinical Coordinator (s) _____
9. The study Investigator's Brochure is attached.
(Required for all investigational drug and device studies.) _____
10. The IND (Investigational New Drug) number is identified (if applicable). _____
11. The IDE (Investigational Device Exemption) number is identified (if applicable). _____
12. The letter from the study sponsor stating that the FDA/HCFA has designated the investigational device as either Category A or Category B is attached (if applicable). _____
13. The DHHS Project Number is identified (if applicable)
(For federally-funded studies, the awardee would have been notified by letter that funds had been awarded. That award letter would also assign a DHHS Project Number). _____
14. Item Grant Budget Provider (required for all federally funded studies) _____
15. The study protocol is attached. _____

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16. The advertisement for study participants is attached (if applicable). _____
17. The questionnaire(s) and/or survey(s) to be used are attached (if applicable) _____
18. The informed consent document is attached and electronic copy supplied. _____
19. The translated consent document is attached and electronic copy supplied.
(Required if using non-English speaking subjects.) _____
20. The NIH-approved sample consent form is attached (if applicable).
(Required for all NIH-sponsored multicenter studies.) _____
21. The Pathology Worksheet (Appendage IV) is attached (required for all studies).
The original has been sent to the Department Director for approval. _____
22. The Pharmacy Worksheet (Appendage III) is attached. (Required for all drug studies.)
The original has been sent to the Department Director for approval. _____
23. The Medical Record Worksheet (Appendage V) is attached and completed
(Required for all chart review studies). The original has been sent to the
Department Director for approval. _____
24. IRB Application Processing Fee \$1500.00 (check attached). _____
25. Letter requesting Waiver of Application fee. _____
26. Corporate Accounting Financial Reporting – Request for Information Form. _____

PLEASE RETURN THIS COMPLETED FORM WITH YOUR APPLICATION