WakeMed Institutional Review Board

NEW STUDY SUBMISSION CHECKLIST

***** Please note that there are 38 items to be checked off on this Checklist. All items must be checked off.*** ***Your submission will not be considered complete until all appropriate forms/documents are submitted and all items are checked on this form.***

****** ALL study staff must have access (shared) to the study on IRBNet prior to submission to the WakeMed IRB. It is up to the PI to determine the level of access to give each staff member.***

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 *INCLUDE IT WITH YOUR APPLICATION*.**

1. **Title of Study:** _____
2. **The Principal Investigator (PI) has electronically signed the IRB Application via IRBNet** _____
3. **Nursing Faculty. Staff and or Nursing Student(s) conducting research have you had your proposed research reviewed by the Director of Nursing Research & EBP? This includes research involving nurses as investigators and/or studying nurses or nursing care. If not, please make an appointment through her assistant at tajones@wakemed.org** _____
4. **Pharmacy Faculty, Residents and or Pharmacy Student(s) conducting research have you had your research reviewed by the Pharmacy Research Consultant? This includes research involving pharmacists as investigators and/or residents. If not, please see the Pharmacy Research Consultant in your department before submitting to the IRB. Note: The Pharmacy Research Consultant must sign off on your project electronically through IRBNet.** _____
5. **The Faculty Sponsor has electronically signed the IRB Application via IRBNet** *(if applicable)* _____
6. **Attach a signed original of HHS/WakeMed Individual Investigator Agreement** _____
7. **Submission of fully-executed Investigator Agreement Page (industry-sponsored studies)** _____
8. **Letters of Support from participating research sites outside of WakeMed, if applicable** _____
9. **Does your project have Any type of external funding? If so, please contact the Office of Grant Research Development prior to your IRB submission at grantsadmin@wakemed.org** _____
10. **For externally funded studies, have you attached the Research Plan and Human Subject Protection components from your grant proposal?** _____
11. **Attach electronically signed, Financial Disclosure form:**
    - Principal Investigator _____
    - Co-investigator(s) _____
    - Clinical Coordinator(s) _____

**** All study staff with Financial Disclosures must electronically sign the submission package via IRBNet.**

12. Copy of the most current Medical Board License for the PI and each co-investigator

Principal Investigator _____

Co-investigator(s) _____

13. Attach copy of Education Training Certificates in Protection of Human Research Subjects:

Principal Investigator _____

Co-investigator(s) _____

Clinical Coordinator(s) _____

14. Attach copy of Curriculum Vitae:

Principal Investigator _____

Co-investigator(s) _____

Clinical Coordinator(s) _____

REQUIRED DRUG/DEVICE INFORMATION

15. Attach current study Investigator's Brochure or IFU/DFU *(if applicable)* _____
(Required for all investigational drug and device studies) for drug studies, if there is no IB, please provide: toxicity data, reports of animal studies and reports of human studies in children and adults.

16. Identify the IND (Investigational New Drug) number *(if applicable)*, **Include a copy of letter from FDA/HHS approving IND application** _____

If the drug is commercially available, did you provide a package insert? _____

17. For IND Studies include signed copy of PI's FDA Form 1572 _____

18. Identify the IDE (Investigational Device Exemption) number *(if applicable)* **include a copy of letter from FDA/HHS approving IDE application** _____

19. For IDE Studies include signed copy of PI's Investigator Agreement with Sponsor

20. If an IDE is required, did you provide the Manufacturer's Notebook (information which Includes the protocol, descriptions of studies done in animals and humans, photographs of the device and information on safety features and safety testing performed)? _____

21. For Investigational Device Studies include copy of the FDA/Medicare agreement to recover costs of the investigational device as either Category A or Category B _____
(if applicable)

22. The DHHS Project Number is identified *(if applicable)* _____
(*For federally-funded studies, the awardee would have been notified by letter that funds have been awarded. That award letter would also be assigned a DHHS Project Number.)*

23. Item Grant Budget Provider identified *(Required for all federally funded studies.)* _____

STANDARD REQUIRED INFORMATION

24. Attached the current fully-completed IRB application _____

25. Does your research involve children, neonates, pregnant women? If so, Did you

Complete the Special Populations Supplemental Application? _____

26. **Attached advertisements for study participants** *(if applicable)* _____

27. **Attached questionnaire(s), survey(s) and/or data tool(s) to be used** *(if applicable)* _____

28. **Attach the WakeMed informed consent document** _____
(HIPAA PHI requirements are met by using the WakeMed informed consent.)

29. **Attached Sponsor consent template** *(if applicable)* _____

30. **Attached translated consent document and local translator's CV** _____
(Required if using non-English speaking subjects, once English consent is approved
***IMPORTANT**: Make sure to obtain certification for all translations from ITS)*

31. **Attached the NIH-approved sample consent form** *(if applicable)* _____
(Required for all NIH-sponsored multicenter studies.)

32. **Chart review studies, submit a Request for Waiver of Informed Consent. If you are collecting PHI a HIPAA Waiver Authorization is also required** _____

33. **Attached the completed Pathology Worksheet (Appendage IV)** *(For all lab requirements)* _____
** It is the responsibility of the P.I. to obtain operational permission prior to submission to the IRB.

34. **Attach the completed approved Pharmacy Worksheet**
(For all drug requirements) ** _____

35. **Attach the completed Medical Record Review Form** _____
(Required for all patient chart reviews paper or electronic.)

36. **IRB Application Processing Fee $2000.00 for initial review or $500.00 for Continuing Review.** *(Please send checks to the WakeMed IRB Office, 3000 New Bern Ave., Raleigh, NC 27610)* _____

37. **Attach Letter requesting Waiver of Application fee** *(if applicable)* _____

38. **Attach Corporate Accounting Financial Reporting – Request for Information Form** _____

39. **Have you read "Conducting Research at WakeMed – IRB Submissions" (found in Library Manager of IRBNet) to ensure your application contains all the relevant necessary documents and information for IRB review?** _____ **YES** **NO** _____

TO AVOID DELAYS, ENSURE ALL SUBMISSIONS ARE COMPLETE and ACCURATE.

Please note: IRB Approval does not imply operational permission from individual departments (i.e., Nursing units, Pathology Laboratory, Cath. Lab, Emergency Room facilities, Medical Records, Radiology etc.) to start the study. It is the Principal Investigator's responsibility to contact each Department Manager affected by the study and to obtain his or her permission to implement the study.