

Principal Investigator: _____

Protocol # _____

Review Guidelines:

This checklist must be completed by the primary and secondary reviewer. It is to be given to the WCGME-IRB Administrator at the conclusion of the meeting and will be filed with the protocol reviewed. (All members of the board are encouraged to complete and submit this checklist for each protocol.)

CHECKLIST USED BY WCGME-IRB FOR REVIEW OF PROPOSALS (revised May 2011)

Regulatory review requirement:	Reviewer input:		
1. The proposed research design is scientifically sound & will not unnecessarily expose subjects to risk.	Yes	No	N/A
a. Is the hypothesis/primary endpoint clear? Is it clearly stated?			
b. Is the study design appropriate to support the hypothesis/primary endpoint?			
c. Will the research contribute to generalizable knowledge and is it worth exposing subjects to risk?			
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may reasonably be expected to result.	Yes	No	N/A
a. Does the Principal Investigator consider the level of risk/discomfort/inconvenience to be greater than minimal?			
b. Does the reviewer agree with the Principal Investigator regarding the level of risk to the patient?			
c. Is there prospect of direct benefit to subjects?			
3. Subject selection is equitable.	Yes	No	N/A
a. Based upon who is to be enrolled(Men? Women? Ethnic minorities? Children (rationale for inclusion/exclusion addressed)? Seriously-ill persons? Healthy volunteers?) is the subject selection equitable?			
b. Are these subjects appropriate for the protocol?			
4. Additional safeguards required for subjects likely to be vulnerable to coercion or undue influence.	Yes	No	N/A
a. Are appropriate protections in place for vulnerable subjects, e.g., pregnant women, fetuses, socially- or economically-disadvantaged, decisionally-impaired?			
5. Informed consent is obtained from research subjects or their legally authorized representative(s).	Yes	No	N/A
a. Does the informed consent document include the eight required elements? (Document requirements are available on the WCGME-IRB Members Resource Page.)			
b. Is the consent document understandable to subjects?			
c. Is the following information listed appropriately in the consent? The person who will obtain informed consent (PI, nurse, other?) and in what setting?			

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d. If appropriate, is there a children's assent?			
e. Is the IRB requested to waive or alter any informed consent requirement?			
6. Risks to subjects are minimized.	Yes	No	N/A
a. Does the research design minimize risks to subjects?			
b. Could use of a data & safety monitoring board or other research oversight process enhance subject safety?			
7. Subject privacy & confidentiality are maximized.	Yes	No	N/A
a. Will personally-identifiable research data be protected to the extent possible from access or use?			
b. Are any special privacy & confidentiality issues properly addressed, e.g., use of genetic information?			

Recommendation: _____

Reviewer's Signature: _____ Date: _____

Reviewer's Name: _____
(Printed or typed)

Place any additional comments below. Use an additional sheet of paper if necessary.